DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2024

Food and Drug Administration

Justification of
Estimates for
Appropriations Committees

On behalf of the U.S. Food and Drug Administration (FDA), I am transmitting FDA's Congressional Justification for the fiscal year (FY) 2024 budget. This request for $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) will be marketed in the U.S. The process involved is rigorous, thoughtful and always adheres to standards for safety and effectiveness. We help to ensure that the human and animal food supply is 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. We also work to ensure the public has the accurate, science-based information needed to make health decisions.

FDA is always in the public eye because the decisions that we make impact so many people every day. But we are now fully into an era in which the vast majority of people have access to the internet, either through increasing availability of high-speed service or the ubiquitous ownership of cell phones. The combination of the COVID-19 pandemic and the rise of misinformation purveyors on this vast new communication landscape have led to substantial societal mistrust in our society's institutions, including FDA. Despite the enormous workload and societal forces that make the mission more challenging, 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. We continue to build on our accomplishments and lessons learned and request new funding to modernize our agency and operations for the future.

The FY 2024 budget for FDA requests a total of $7.2 billion in annual funding. This represents an increase of $372 million in direct discretionary budget authority. These critical investments will help us address our most urgent public health priorities, strengthen our public health capacity and business operations, advance agency-wide IT modernization capabilities, and improve our agency-wide infrastructure. The budget proposes $150 million in additional user fees and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. The budget also requests $670 million in mandatory funding to better prepare FDA to combat the next pandemic.

The budget also provides a historic investment to strengthen FDA's food safety and nutrition capacity, demonstrating the Administration's ongoing commitment to these responsibilities. FDA recently announced a new, transformative vision for the FDA Human Foods Program as a result of findings and recommendations identified through the external evaluation[1] conducted by an expert panel of the Reagan-Udall Foundation and the separate internal review[2] of the agency's infant formula supply chain response. While structural and process changes are in progress, there is still a significant need for additional resources to strengthen the Agency's foundational capacity. The Budget complements this vision and provides targeted investments in activities that will protect and promote a safe, nutritious U.S. food supply.

We take our public health mandate seriously, and our focus is always on the well-being of patients and consumers. On behalf of FDA, I extend my thanks for your support of FDA's mission and FY 2024 budget priorities.

Sincerely,

Robert Califf, M.D.
Commissioner, Food and Drug Administration

[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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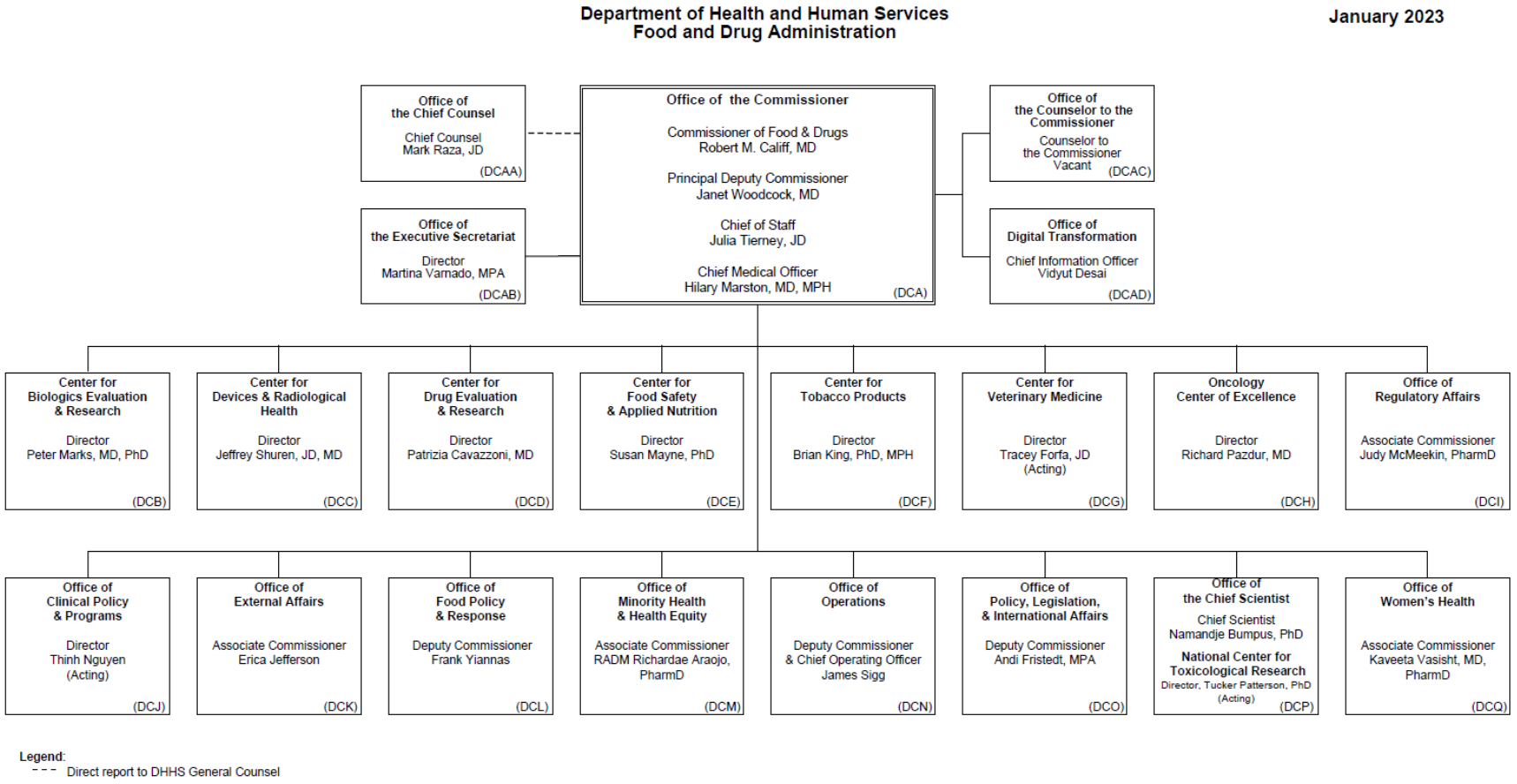
FDA ORGANIZATION CHART



FY 2024 EXECUTIVE SUMMARY

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 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 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:

- Advancing health equity through outreach, collaborative research, and regulatory efforts;
- Enable 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 improve public health;
- Modernizing legacy information technology infrastructure, processes, and systems to deploy emerging technologies, such as artificial intelligence and machine learning; and
- Advancing strong strategic management to foster prudent use of resources, strengthen human capital management, and enhance public trust. This includes continuing to employ Enterprise Risk Management practices to assess, prioritize, manage, and oversee the Agency's top risks. FDA's approach aims to identify and implement strategies that help mitigate the challenges s to accomplishing the Agency's public health mission and goals that these risks, as well as emerging risks, present.

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 are informed about FDA's intended outcomes to better understand diverse patient perspectives, preferences, and unmet needs.

OVERVIEW OF FY 2024 PRESIDENT'S BUDGET

As the oldest comprehensive consumer protection agency in the country for more than a century, the 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) 2024 request for FDA to the Congress 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.

The FY 2024 Budget reflects an overall increase of 7.8 percent or $521.4 million above FY 2023 Enacted. This includes $3.96 billion in budget authority, an increase of 10.4 percent or $371.9 million, and $3.3 billion in user fees, an increase of 4.8 percent or $149.5 million. The Budget requests a total of $1.7 billion for human food, animal food, nutrition, and cosmetics work and $4.6 billion for medical product safety activities.

(Dollars in Thousands)	FY 2023 Enacted			FY 2024 President's Budget			President's Budget +/- FY 2023 Enacted		
	Food Safety	Medical Product Safety	Total*	Food Safety	Medical Product Safety	Total*	Food Safety	Medical Product Safety	Total
Total Budget Authority Post Transfer	1,519,952	1,992,784	3,591,438	1,730,183	2,143,721	3,963,316	210,231	150,937	371,878
Total User Fees	17,086	2,388,655	3,128,632	17,428	2,437,630	3,278,167	342	48,975	149,535
Total Program Level	1,537,038	4,381,439	6,720,070	1,747,611	4,581,351	7,241,483	210,573	199,912	521,413

*Food Safety total is inclusive of Human Food, Animal Food, Nutrition, and Cosmetics
*BA total include White Oak Campus, Buildings and Facilities, China Initiative and Hight Risk Foreign Inspections which are not part of FS or MPS
*UF totals include Tobacco and Color Certification user fees estimates which are not part of FS or MPS

Figure 1 - Overview of FY 2024 President's Budget

The funding and programmatic approaches described in the request are compared to the FY 203 Enacted level. The Budget invests in new and expanded activities and is broken down into six areas in support of protecting and promoting public health:

- **Enhancing Food Safety, Nutrition, and Cosmetics** – ensures the human and animal food supply is safe, sanitary, wholesome, and accurately labeled, and that cosmetic products are safe and properly 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 U.S., including medical countermeasures.
- **Investing in Core Operations** – provides crosscutting enterprise-wide policy, legal, information technology (IT), 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 $371.9 million in direct discretionary budget authority, which reflects a 10.4 percent increase above FY 2023 Enacted. These critical discretionary investments will help us address our most urgent human and animal 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 2024 Budget includes the following changes:

(Dollars in Millions)	FY 2023	FY 2024	
	Enacted	President's Budget	President's Budget +/- Enacted
Budget Authority /1	**3,591.4**	**3,963.3**	**371.9**
Program Level /2	**6,720.1**	**7,241.5**	**521.4**
Enhancing Food Safety, Nutrition and Cosmetics	**39.8**	**173.0**	**133.2**
Healthy and Safe Food for All	-	64.0	+64.0
Nutrition and Labeling	-	12.0	+12.0
New Era of Smarter Food Safety	3.5	40.5	+37.0
Food Supply Chain Continuity	-	5.0	+5.0
Emerging Chemical and Toxicological Issues	15.0	20.0	+5.0
Animal Food Safety Lifecycle	21.3	26.5	+5.2
Modernization of Cosmetics Implementation	-	5.0	+5.0
Advancing Safe & Effective Medical Products	**167.2**	**265.4**	**98.2**
Postmarket Safety Collaborative	26.7	36.8	+10.1
ACT for ALS	5.0	7.5	+2.5
Advancing the Goal of Ending the Opioid Crisis	79.5	102.5	+23.0
Device Shortages & Supply Chain	10.0	21.6	+11.6
Medical Product Safety Data Modernization	44.0	47.0	+3.0
Reigniting Cancer Moonshot	2.0	50.0	+48.0
Strengthening FDA's Public Health & Mission Support Capacity	**39.5**	**170.6**	**131.1**
Public Health Employee Pay Costs	-	105.3	+105.3
OC Regulatory and Mission Support	21.5	37.3	+15.8
Enterprise Data and IT Modernization	18.0	28.0	+10.0
Infrastructure: Facilities Investments and Rent	**333.6**	**343.0**	**9.4**
White Oak	48.4	49.0	+0.6
Other Rent and Rent Related	106.1	118.5	+12.4
GSA Rental Payments	166.3	156.7	-9.60
Buildings and Facilities	12.8	18.8	+6.0

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.

Figure 2 - Discretionary Budget Authority Overview

FY 2024 BUDGET

ENHANCING FOOD SAFETY, NUTRITION, AND COSMETICS

The Budget provides $1.7 billion for food safety, nutrition, and cosmetics, an increase of 13.7 percent or +$210.6 million above FY 2023, to support our continued efforts and commitment to strengthen FDA's food safety and nutrition capacity. This total includes $1.7 billion in budget authority and $17.0 million in user fees.

The Budget provides a historic investment to strengthen FDA's food safety and nutrition capacity. As FDA regulates approximately 80% of foods consumed by Americans, including those bought in grocery stores, restaurants, and cafeterias, FDA is seeking resources to strengthen consumer protection and implement lasting solutions to make operations more efficient in the future. This Budget demonstrates the Administration's ongoing commitment to FDA's food safety and nutrition portfolio. The Budget will help ensure our human and animal food supplies are safe, sanitary, wholesome, and accurately labeled, which now includes additional cosmetic products oversight for safety and proper labeling.

In late January 2023, FDA announced a new, transformative vision for the FDA Human Foods Program as a result of findings and recommendations identified through the external evaluation[3] conducted by an expert panel of the Reagan-Udall Foundation and the separate internal review[4] of the Agency's infant formula supply chain response. While structural and process changes are in progress, there is still a significant need for additional resources to strengthen the Agency's foundational capacity to address food safety, nutrition work, and cosmetics oversight. The Budget complements this vision and provides initial targeted investments in activities that will help protect and promote a safe, nutritious U.S. food supply.

With this Budget, FDA is seeking resources to continue efforts of providing safe and healthy food. The infant formula shortage serves as an example demanding greater attention and scrutiny of critical food safety, security, and accessibility issues, clearly including those of nutritional importance. To enhance its capabilities, FDA is requesting funding to modernize infant formula oversight, empower consumers to make healthier food choices, and reduce exposure to toxic chemicals in the food supply.

Further, the Budget will increase FDA's inspections capabilities, including risk-based oversight of human and animal food facilities subject to FDA's food safety regulations and related capabilities to strengthen our assessment of the health of supply chains and to inform efforts to better respond to shortages of critical foods. The Budget also will allow FDA continue modernizing FDA's oversight of the vast and growing $80+ billion cosmetics industry.

The Budget requests new budget authority for the following:

- **Healthy and Safe Food for All:** +$64.0 million to modernize oversight of infant formula, empower consumers to make healthier food choices, reduce exposure to toxic chemicals, and implement new regulatory authorities for both cosmetics and dietary supplements.

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

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

- **Nutrition and Labeling:** +$12.0 million to strengthen nutrition and labeling work in alignment with the White House's National Strategy on Hunger, Nutrition, and Health.

- **New Era of Smarter Food Safety**: +$37.0 million, for a total of $40.5 million, to strengthen data access and analysis capabilities and capacity, further support expansion of the GenomeTrakr, and further food safety inspection capabilities.

- **Food Supply Chain Continuity:** +$5.0 million for food supply chain continuity investments and capacity that will strengthen the agency's ability to assess the health of supply chains and inform efforts to respond to shortages of critical foods.

- **Emerging Chemical and Toxicological Issues:** +$5.0 million, for a total of $20.0 million, to support food safety programs that fall mostly outside of FSMA's purview, to enhance and update FDA's approach to chemicals—both those directly added as food ingredients and those that come into the food supply through food contact.

- **Animal Food Safety Lifecycle:** +$5.2 million, for a total of $26.5 million, to increase FDA's capacity to conduct premarket reviews of innovative animal food ingredients, while advancing the risk-based-oversight of domestic animal food facilities subject to FDA's food safety regulations, including FSMA.

- **Modernization of Cosmetics Implementation:** +$5.0 million to develop regulations, compliance policies, and related submission platforms for registration and product listing, adverse event reporting, talc-containing cosmetics, labeling, and current Good Manufacturing Practices.

Additional information on this request may be found within the various Program chapters on pages 47 (Foods Program), 112 (Animal Drugs and Foods Program), 168 (Field), and 210 (Headquarters).

ADVANCING SAFE & EFFECTIVE MEDICAL PRODUCTS

The Budget provides $4.6 billion for medical product safety, an increase of 4.6 percent or +$199.9 million above FY 2023. This total includes $2.1 billion in budget authority and $2.4 billion in user fees.

The Budget provides funding to advance efforts to strengthen medical product safety and availability across FDA's medical product Centers. The Budget includes funding to strengthen the performance, safety, and effectiveness of medical products, support resilience in the medical supply chain for devices, and funding to support public health programs to combat the opioid epidemic. The Budget also provides funding to support the implementation of the Accelerating Access to Critical Therapies (ACT) for Amyotrophic Lateral Sclerosis (ALS)[5]. The Budget includes the following:

[5] ACT for ALS is the common name for, "Accelerating Access to Critical Therapies for ALS Act." Public Law No. 117-79.

- **Postmarket Safety Collaborative:** +$10.1 million for a total of $36.8 million to enhance safety surveillance and oversight programs to develop more efficient and effective detection, evaluation, prevention, and mitigation of adverse events. Protecting the health of humans and animals requires FDA to continuously enhance its safety surveillance and oversight programs, consistent with advances in the science of drug and device safety. New scientific approaches and improved tools are available and needed for the efficient and effective detection, evaluation, prevention, and mitigation of adverse events.

- **ACT for ALS:** +$2.5 million for a total of $7.5 million to implement the ACT for ALS, including the ability to issue new grants and contracts, hire dedicated expert staff, and allow FDA to facilitate access to investigational therapies and medical devices for neurodegenerative diseases such as amyotrophic lateral sclerosis (i.e., ALS, also known as Lou Gehrig's disease, a progressive and fatal disease).

- **Advancing the Goal of Ending the Opioid Crisis**: +$23.0 million, for a total of $102.5 million, for broaden the development of opioid overdose reversal treatments and treatments for substance use disorders; to expand compliance, enforcement, and laboratory support along with expanding FDA's use of field deployable analytical tools and satellite laboratories; and to advance the development, evaluation, and market authorization of digital health medical devices.

- **Device Shortages and Supply Chain:** +$11.6 million, for a total of $21.6 million, to continue building capabilities for FDA's Resilient Supply Chain and Shortages Program for medical devices. This program will work proactively with medical device companies, health care providers, device distributors, patients, and the to enhance resiliency in the supply chain of critical medical devices and prevent shortages of critical devices that most often impact vulnerable populations, and continue to support U.S. government efforts to assure patients have access to devices during public health emergencies, as well as every day in our healthcare system.

- **Medical Product Safety Data Modernization:** +$3.0 million, for a total of $47.0 million, to strengthen data modernization platforms and capabilities in alignment with FDA's overall strategy to modernize IT platforms and technological capabilities. The funds will strengthen the Devices Program's Digital Transformation initiative, improve information management and data infrastructure for scientifically complex biologics, and modernize outdated and disparate IT processes and provide flexibility to meet the challenges of an evolving animal product regulatory landscape.

Additional information on this request may be found within the various Program chapters on pages 71 (Human Drugs Program), 90 (Biologics Program), 112 (Animal Drugs and Foods Program), 131 (Devices Program), 168 (Field), and 210 (Headquarters).

REIGNITING CANCER MOONSHOT

The Budget provides $50.0 million for FDA to advance the President's Cancer Moonshot goals. These funds will enhance efforts to expand resources and collaborations to improve evidence generation for underrepresented subgroups in oncology clinical trials, and to support pragmatic

and decentralized trials and our sources of evidence through patient-generated data, learnings, and real-world evidence. Additionally, these resources will also assist FDA's to expansion of its efforts to facilitate the approvals of innovative and new cancer treatments by international regulatory authorities at the time of FDA approval and will foster collaboration of cancer treatments in other countries with standards comparable to the U.S. standard of care.

Additional information may be found within the Headquarters chapter on page 210.

STRENGTHENING FDA'S PUBLIC HEALTH & MISSION SUPPORT CAPACITY

The Budget provides $131.1 million in additional budget authority above the FY 2023 Enacted level to strengthen FDA's public health mission and support capacity. The Budget provides full funding, for the first time, the anticipated increase in FDA's public health employee pay costs, and will help the agency better manage several of its top, longer-standing risks. The Budget also expands on FDA's data and IT infrastructure modernization efforts and strengthens central enterprise-wide business and policy services within the Office of the Commissioner.

The Budget includes the following:

- **Public Health Employee Pay Costs:** +$105.3 million in new budget authority to fully fund, for the first time, the anticipated increases in FDA's public health employee pay costs. This increase will support the annualization of the 2023 4.6 percent Cost of Living pay increase and the 2024 5.2 percent Cost of Living pay increase. In FY 2022, over 50% of FDA's annual spending, including budget authority and user fees, funded payroll and benefits for more than 19,000 people. The inflationary pay cost requested in the Budget will support staff within all of FDA's Offices and Centers that receive Budget Authority funding and provide the full anticipated pay increase in FY 2024.

- **Office of the Commissioner Regulatory and Mission Support:** +$15.8 million to advance the highest priority Regulatory Capacity and Mission Support functions within the Office of the Commissioner (OC). These resources will enable FDA to provide the appropriate crosscutting strategic direction, policy coordination, and business services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. The funds will increase FDA's regulatory and policy development and coordination capacity, provide funding for a new Enterprise Transformation effort, enhance cannabis product regulatory policy coordination work, expand the New Alternative Methods Program strategic oversight, and provide additional funding for Essential Services through the Working Capital Fund. The Budget builds on prior investments to provide targeted regulatory capacity to advance emerging programmatic areas and mission support business services to ensure that OC can keep pace with the continued annual growth of Centers and Field programmatic operations.

- **Enterprise Data and IT Modernization:** +$10.0 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.

For additional information about these investments, see the Headquarters chapter on page 210.

INFRASTRUCTURE AND BUILDINGS & FACILITIES

The Budget provides $485.6 million for infrastructure, buildings and facilities, an increase of 1.5 percent or +$7.0 million above FY 2023 Enacted. This total includes $395.9 million in budget authority and $89.7 million in user fees. The Budget reflects a reallocation of funding between budget authority and user fees to reflect a change in the infrastructure accounts and the comparisons reflect increases after those reallocation levels.

The Budget provides funding to help ensure that FDA's offices and labs across the country and its fully integrated White Oak Campus are optimally functioning and enable FDA to carry out its mission, evaluate food safety and medical products, and respond to emergencies. This will directly support FDA's priorities by providing secure, modern, reliable, and cost-effective office and laboratory space that empowers FDA's workforce to protect and promote the safety and health of American families. Investing in FDA's facility objectives will provide the high-quality infrastructure and facilities needed for FDA employees to work to ensure FDA can achieve its strategic priorities. The Budget includes:

- **General Services Administration (GSA) Rent:** A reduction of -$9.6 million, for a total of $156.7 million, to meet FDA's rent obligations. It includes estimates for rent changes associated with continuing occupancies for which renewal rents will reset to market.

- **Other Rent & Rent-Related:** +$61.2 million for a total of $167.3 million to offset the user-fee reductions required to comply with changes to the FDA Reauthorization Act of 2017 Section 905 and allow FDA to meet its obligations associated with the Other Rent & Rent-Related account including costs for operating, maintaining, and securing FDA and GSA facilities located nationwide. This offset results in a net zero impact.

- **White Oak Campus:** +$4.7 million for a total of $53.1 million to offset the user-fee reductions required to comply with FDARA Section 905 and support operations at FDA's White Oak Campus, infrastructure improvements above GSA-standard, and specific support for above-standard infrastructure needs associated with the laboratory-building infrastructure, such as recommissioning and correcting identified deficiencies.

- **Buildings and Facilities:** +$6.0 million for a total of $18.8 million to improve and modernize the condition of FDA's owned buildings and infrastructure and meet program needs.

Additional information on this request may be found within the Infrastructure and B&F Program chapters beginning on pages 243 and 254.

TOBACCO REGULATION

The Budget provides $780.0 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 $100.0 million in user fees and requests authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. These products represent an increasing share of FDA's tobacco regulatory activities. The 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. To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation. 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.

Tobacco product regulation represents one of FDA's greatest opportunities to save lives. The Tobacco Control Act gave FDA immediate authority to regulate cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. FDA finalized the Deeming rule in 2016, which extended FDA's tobacco authorities to all tobacco products, including cigars, hookah (waterpipe) tobacco, pipe tobacco, nicotine gels, and e-cigarettes. FDA regulates the manufacture, marketing, and distribution of tobacco products. In 2022, an important new federal law went into effect clarifying FDA's authority to regulate tobacco products containing nicotine from any source, including synthetic or non-tobacco nicotine (NTN)—that is, nicotine not made or derived from tobacco.

FDA continues its critical work of reviewing new tobacco product applications before those products can be legally marketed. This is a sizable task given the sheer volume of applications and the rapidly evolving tobacco landscape, but the Agency has been working diligently to ensure applications are processed as quickly as possible while also ensuring that decisions are scientifically accurate, legally defensible, and aligned with the authorities granted by Congress. And while the FDA's application review is ongoing, 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, including NTN products, especially those used prominently by youth.

Additional information on this request may be found within Tobacco Program chapter on page 191.

LEGISLATIVE PROPOSALS

The FY 2024 Budget includes several legislative proposals that better support Agency efforts to protect American consumers and patients, particularly during public health emergencies like the COVID-19 pandemic. The proposals include enhanced authorities related to shortages of drugs, medical devices, and foods, particularly requirements for manufacturers to notify FDA when they will be unable to supply an increase in demand; additional tools to allow FDA to continue certain oversight activities when inspections are not feasible; expanded authorities for information sharing with the states; and additional authorities for destruction of products which present a significant public health concern. The Budget also proposes new authorities which would require animal drug sponsors to make post-approval safety changes, better support our Closer to Zero initiative and protect infants and young children from exposure to toxic elements, and expand FDA's mandatory recall authority to cover all human and animal drugs. Finally, the Budget would provide FDA with additional authorities to increase oversight of dietary

supplements to better protect consumers and to modernize the tobacco user fee framework to allow for a fair distribution of tobacco user fee assessments to all regulated tobacco products.

Additional information on the legislative proposals may be found on page 37.

PANDEMIC PREPAREDNESS

The COVID-19 pandemic has reiterated FDA's unique and cross-cutting role, which is 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 any future pandemic or internationally significant biological incident. 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 would 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 inter-connectedness 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.

And 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 now to build on lessons learned and provide transformational investments to help ensure that FDA can respond quickly and effectively in times of a public health crisis.

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

TECHNICAL NOTES

The FY 2024 Budget includes three net zero alignments of funding:

Comparability Adjustment

The FY 2024 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.

FDA Infrastructure Costs Realignment

The FY 2024 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 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Foods	**3,923**	**1,143,206**	**3,969**	**1,207,864**	**4,164**	**1,360,855**	**195**	**152,991**
Budget Authority	***3,879***	***1,131,670***	***3,925***	***1,196,097***	***4,120***	***1,348,852***	***195***	***152,755***
User Fees	***44***	***11,536***	***44***	***11,767***	***44***	***12,003***	***---***	***236***
Center	1,190	368,057	1,227	402,768	1,362	509,542	135	106,774
Budget Authority	1,187	367,174	1,224	401,867	1,359	508,623	135	106,756
User Fees	3	883	3	901	3	919	---	18
Food and Feed Recall	1	258	1	263	1	268	---	5
Voluntary Qualified Importer Program	1	258	1	263	1	268	---	5
Third Party Auditor Program	1	367	1	375	1	383	---	8
Field	2,733	775,149	2,742	805,096	2,802	851,313	60	46,217
Budget Authority	2,692	764,496	2,701	794,230	2,761	840,229	60	45,999
User Fees	41	10,653	41	10,866	41	11,084	---	218
Food and Feed Recall	4	1,061	4	1,082	4	1,104	---	22
Food Reinspection	19	4,855	19	4,952	19	5,051	---	99
Voluntary Qualified Importer Program	18	4,584	18	4,676	18	4,770	---	94
Third Party Auditor Program	---	153	---	156	---	159	---	3
Human Drugs	**6,782**	**2,116,644**	**6,825**	**2,282,747**	**6,847**	**2,381,802**	**22**	**99,055**
Budget Authority	***2,119***	***714,446***	***2,162***	***760,494***	***2,184***	***775,446***	***22***	***14,952***
User Fees	***4,663***	***1,402,198***	***4,663***	***1,522,253***	***4,663***	***1,606,356***	***---***	***84,103***
Center	5,712	1,851,926	5,738	1,998,525	5,759	2,087,880	21	89,355
Budget Authority	1,327	518,135	1,353	549,993	1,374	560,040	21	10,047
User Fees	4,385	1,333,791	4,385	1,448,532	4,385	1,527,840	---	79,308
Prescription Drug (PDUFA)	2,863	878,206	2,863	958,619	2,863	1,007,152	---	48,533
Generic Drug (GDUFA)	1,410	419,210	1,410	452,136	1,410	480,603	---	28,467
Biosimilars (BsUFA)	110	35,709	110	37,097	110	39,392	---	2,295
Outsourcing Facility	2	666	2	680	2	693	---	13
Field	1,070	264,718	1,087	284,222	1,088	293,922	1	9,700
Budget Authority	792	196,311	809	210,501	810	215,406	1	4,905
User Fees	278	68,407	278	73,721	278	78,516	---	4,795
Prescription Drug (PDUFA)	43	9,312	43	10,167	43	10,872	---	705
Generic Drug (GDUFA)	226	57,205	226	61,598	226	65,537	---	3,939
Biosimilars (BsUFA)	7	1,487	7	1,545	7	1,687	---	142
Outsourcing Facility	2	403	2	411	2	420	---	9

Figure 3 - All-Purpose Table 1/6

(Dollars in Thousands)	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Biologics	**1,458**	**456,717**	**1,465**	**489,765**	**1,469**	**509,255**	**4**	**19,490**
Budget Authority	***824***	***259,953***	***831***	***271,515***	***835***	***277,570***	***4***	***6,055***
User Fees	***634***	***196,764***	***634***	***218,250***	***634***	***231,685***	***---***	***13,435***
Center	1,222	410,004	1,225	439,629	1,229	457,364	4	17,735
Budget Authority	595	215,127	598	223,465	602	228,128	4	4,663
User Fees	627	194,877	627	216,164	627	229,236	---	13,072
Prescription Drug (PDUFA)	566	178,620	566	194,934	566	206,308	---	11,374
Medical Device (MDUFA)	56	14,886	56	19,857	56	21,353	---	1,496
Generic Drug (GDUFA)	4	1,103	4	1,094	4	1,148	---	54
Biosimilars (BsUFA)	1	268	1	279	1	427	---	148
Field	236	46,713	240	50,136	240	51,891	---	1,755
Budget Authority	229	44,826	233	48,050	233	49,442	---	1,392
User Fees	7	1,887	7	2,086	7	2,449	---	363
Prescription Drug (PDUFA)	6	1,649	6	1,768	6	2,054	---	286
Medical Device (MDUFA)	1	238	1	318	1	395	---	77
Animal Drugs and Foods	**1,023**	**255,973**	**1,066**	**288,353**	**1,131**	**313,958**	**65**	**25,605**
Budget Authority	***841***	***202,535***	***874***	***230,093***	***939***	***257,689***	***65***	***27,596***
User Fees	***182***	***53,438***	***192***	***58,260***	***192***	***56,269***	***---***	***-1,991***
Center	706	182,056	739	204,730	800	226,914	61	22,184
Budget Authority	530	130,111	553	148,141	614	172,423	61	24,282
User Fees	176	51,945	186	56,589	186	54,491	---	-2,098
Animal Drug (ADUFA)	115	28,648	115	29,100	115	30,436	---	1,336
Animal Generic Drug (AGDUFA)	61	23,178	71	27,368	71	23,932	---	-3,436
Third Party Auditor Program	---	119	---	121	---	123	---	2
Field	317	73,917	327	83,623	331	87,044	4	3,421
Budget Authority	311	72,424	321	81,952	325	85,266	4	3,314
User Fees	6	1,493	6	1,671	6	1,778	---	107
Animal Drug (ADUFA)	2	393	2	400	2	438	---	38
Animal Generic Drug (AGDUFA)	1	244	1	397	1	449	---	52
Food Reinspection	3	856	3	874	3	891	---	17
Third Party Auditor Program	---	---	---	---	---	---	---	---

Figure 4 - All-Purpose Table 2/6

(Dollars in Thousands)	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Devices and Radiological Health	**2,356**	**647,467**	**2,516**	**745,949**	**2,574**	**791,857**	**58**	**45,908**
Budget Authority	***1,519***	***419,457***	***1,538***	***449,297***	***1,554***	***477,990***	***16***	***28,693***
User Fees	***837***	***228,010***	***978***	***296,652***	***1,020***	***313,867***	***42***	***17,215***
Center	1,845	545,670	2,001	637,459	2,061	679,046	60	41,587
Budget Authority	1,028	331,904	1,043	356,062	1,061	380,952	18	24,890
User Fees	817	213,766	958	281,397	1,000	298,094	42	16,697
Prescription Drug (PDUFA)	15	5,361	15	5,652	15	9,164	---	3,512
Medical Device (MDUFA)	774	201,228	915	268,425	957	281,463	42	13,038
Mammography Quality Standards Act (MQSA)	28	7,177	28	7,320	28	7,467	---	147
Field	511	101,797	515	108,490	513	112,811	-2	4,321
Budget Authority	491	87,553	495	93,235	493	97,038	-2	3,803
User Fees	20	14,244	20	15,255	20	15,773	---	518
Medical Device (MDUFA)	11	2,507	11	3,283	11	3,562	---	279
Mammography Quality Standards Act (MQSA)	9	11,737	9	11,972	9	12,211	---	239
National Center for Toxicological Research (BA Only)	**276**	**70,391**	**286**	**76,919**	**286**	**80,154**	**---**	**3,235**
Tobacco	**1,287**	**679,944**	**1,303**	**677,165**	**1,312**	**779,965**	**9**	**102,800**
Center	**1,202**	**652,459**	**1,218**	**654,671**	**1,219**	**748,687**	**1**	**94,016**
User Fees	1,202	652,459	1,218	654,671	1,219	748,687	1	94,016
Family Smoking Prevention and Tobacco Control Act	1,202	652,459	1,218	654,671	1,219	648,687	1	-5,984
Expand tobacco products (Proposed)	---	---	---	---	---	100,000	---	100,000
Field	**85**	**27,485**	**85**	**22,494**	**93**	**31,278**	**8**	**8,784**
Family Smoking Prevention and Tobacco Control Act	85	27,485	85	22,494	93	31,278	8	8,784
FDA Headquarters	**941**	**331,099**	**963**	**364,323**	**1,072**	**423,031**	**109**	**58,708**
Budget Authority	530	205,981	550	224,940	657	301,264	107	76,324
User Fees	***411***	***125,118***	***413***	***139,383***	***415***	***121,767***	***2***	***-17,616***
Prescription Drug (PDUFA)	215	59,725	215	65,747	215	60,355	---	-5,392
Medical Device (MDUFA)	36	10,652	36	14,271	36	12,786	---	-1,485
Generic Drug (GDUFA)	100	35,561	100	38,986	100	32,414	---	-6,572
Biosimilars (BsUFA)	8	1,009	8	1,051	8	433	---	-618
Animal Drug (ADUFA)	4	937	4	954	4	864	---	-90
Animal Generic Drug (AGDUFA)	3	788	3	949	3	117	---	-832
Family Smoking Prevention and Tobacco Control Act	41	14,999	43	15,949	45	13,293	2	-2,656
Mammography Quality Standards Act (MQSA)	---	77	---	79	---	80	---	1
Food and Feed Recall	---	80	---	81	---	83	---	2
Food Reinspection	2	509	2	519	2	529	---	10
Voluntary Qualified Importer Program	1	294	1	300	1	306	---	6
Third Party Auditor Program	---	41	---	42	---	43	---	1
Outsourcing Facility	1	446	1	455	1	464	---	9

Figure 5 - All-Purpose Table 3/6

(Dollars in Thousands)	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
FDA White Oak Campus	**---**	**53,832**	**---**	**56,293**	**---**	**57,037**	**---**	**744**
Budget Authority	---	46,664	---	48,414	---	53,124	---	4,710
User Fees	***---***	***7,168***	***---***	***7,879***	***---***	***3,913***	***---***	***-3,966***
Prescription Drug (PDUFA)	---	3,925	---	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	---	3,243	---	3,593	---	3,913	---	320
Other Rent and Rent Related	**---**	**153,062**	**---**	**164,550**	**---**	**173,845**	**---**	**9,295**
Budget Authority	---	99,762	---	106,095	---	167,253	---	61,158
User Fees	***---***	***53,300***	***---***	***58,455***	***---***	***6,592***	***---***	***-51,863***
Prescription Drug (PDUFA)	---	26,919	---	29,391	---	---	---	-29,391
Medical Device (MDUFA)	---	5,398	---	7,200	---	---	---	-7,200
Generic Drug (GDUFA)	---	13,472	---	14,541	---	---	---	-14,541
Biosimilars (BsUFA)	---	1,102	---	1,145	---	---	---	-1,145
Animal Drug (ADUFA)	---	806	---	820	---	855	---	35
Animal Generic Drug (AGDUFA)	---	272	---	272	---	232	---	-40
Family Smoking Prevention and Tobacco Control Act	---	4,828	---	4,572	---	4,980	---	408
Food and Feed Recall	---	46	---	47	---	48	---	1
Food Reinspection	---	216	---	220	---	224	---	4
Voluntary Qualified Importer Program	---	180	---	184	---	188	---	4
Third Party Auditor Program	---	25	---	26	---	27	---	1
Outsourcing Facility	---	36	---	37	---	38	---	1
GSA Rental Payments	**---**	**222,857**	**---**	**244,884**	**---**	**235,888**	**---**	**-8,996**
Budget Authority	---	153,286	---	166,286	---	156,686	---	-9,600
User Fees	***---***	***69,571***	***---***	***78,598***	***---***	***79,202***	***---***	***604***
Prescription Drug (PDUFA)	---	36,412	---	39,755	---	40,620	---	865
Medical Device (MDUFA)	---	8,564	---	11,423	---	11,714	---	291
Generic Drug (GDUFA)	---	13,105	---	14,145	---	14,448	---	303
Biosimilars (BsUFA)	---	465	---	483	---	493	---	10
Animal Drug (ADUFA)	---	857	---	870	---	907	---	37
Animal Generic Drug (AGDUFA)	---	316	---	317	---	270	---	-47
Family Smoking Prevention and Tobacco Control Act	---	8,986	---	10,721	---	9,849	---	-872
Food and Feed Recall	---	77	---	79	---	81	---	2
Food Reinspection	---	369	---	377	---	384	---	7
Voluntary Qualified Importer Program	---	308	---	314	---	320	---	6
Third Party Auditor Program	---	50	---	51	---	52	---	1
Outsourcing Facility	---	62	---	63	---	64	---	1

Figure 6 - All-Purpose Table 4/6

(Dollars in Thousands)	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Color Certification	37	10,678	37	10,891	37	11,109	---	218
Export Certification	26	4,983	26	5,083	26	5,185	---	102
Export Certification (Proposed)	---	---	---	---	---	4,542	---	4,542
Priority Review Vouchers (PRV) Tropical Disease	---	2,608	---	2,660	---	2,713	---	53
Priority Review Vouchers (PRV) Pediatric Disease	11	8,156	11	8,320	11	8,486	---	166
Priority Review Vouchers (PRV) Medical Countermeasures	---	2,608	---	2,660	---	2,713	---	53
Over the Counter Monograph	---	28,968	---	30,356	---	31,800	---	1,444
21st Century Cures (BA Only)	187	50,000	187	50,000	187	50,000	---	---
Subtotal, Salaries and Expenses	**18,307**	**6,239,193**	**18,654**	**6,708,782**	**19,116**	**7,224,195**	**462**	**515,413**
Buildings and Facilities (Budget Authority)	**---**	**12,788**	**---**	**12,788**	**---**	**18,788**	**---**	**6,000**
Total Program Level	**18,307**	**6,251,981**	**18,654**	**6,721,570**	**19,116**	**7,242,983**	**462**	**521,413**
Non-Field Activities	*13,168*	*4,469,663*	*13,471*	*4,838,994*	*13,862*	*5,279,166*	*391*	*440,172*
Field Activities	*4,952*	*1,289,779*	*4,996*	*1,354,061*	*5,067*	*1,428,259*	*71*	*74,198*
White Oak, Rent Activities, and B&F	---	*442,539*	---	*478,515*	---	*485,558*	---	*7,043*
21st Century Cures	*187*	*50,000*	*187*	*50,000*	*187*	*50,000*	---	---
User Fees:								
Current Law								
Prescription Drug (PDUFA)	*3,708*	*1,200,129*	*3,708*	*1,310,319*	*3,708*	*1,336,525*	---	*26,206*
Medical Device (MDUFA)	*878*	*243,473*	*1,019*	*324,777*	*1,061*	*331,273*	*42*	*6,496*
Generic Drug (GDUFA)	*1,740*	*539,656*	*1,740*	*582,500*	*1,740*	*594,150*	---	*11,650*
Biosimilars (BsUFA)	*126*	*40,040*	*126*	*41,600*	*126*	*42,432*	---	*832*
Animal Drug (ADUFA)	*121*	*31,641*	*121*	*32,144*	*121*	*33,500*	---	*1,356*
Animal Generic Drug (AGDUFA)	*65*	*24,798*	*75*	*29,303*	*75*	*25,000*	---	*-4,303*
Family Smoking Prevention and Tobacco Control Act	*1,328*	*712,000*	*1,346*	*712,000*	*1,357*	*712,000*	*11*	---
Subtotal, Current Law	**7,966**	**2,791,737**	**8,135**	**3,032,643**	**8,188**	**3,074,880**	**53**	**42,237**

Figure 7 - All-Purpose Table 5/6

(Dollars in Thousands)	FY 2022 Final		FY 2023 Enacted		FY 2024 President's Budget		FY 2024 President's Budget +/- FY 2023 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Indefinite								
Mammography Quality Standards Act (MQSA)	*37*	*18,991*	*37*	*19,371*	*37*	*19,758*	---	*387*
Color Certification	*37*	*10,678*	*37*	*10,891*	*37*	*11,109*	---	*218*
Export Certification	*26*	*4,983*	*26*	*5,083*	*26*	*5,185*	---	*102*
Priority Review Vouchers (PRV) Tropical Disease	---	*2,608*	---	*2,660*	---	*2,713*	---	*53*
Priority Review Vouchers (PRV) Pediatric Disease	*11*	*8,156*	*11*	*8,320*	*11*	*8,486*	---	*166*
Priority Review Vouchers (PRV) Medical Countermeasures	---	*2,608*	---	*2,660*	---	*2,713*	---	*53*
Food and Feed Recall	*5*	*1,522*	*5*	*1,552*	*5*	*1,584*	---	*32*
Food Reinspection	*24*	*6,805*	*24*	*6,942*	*24*	*7,079*	---	*137*
Voluntary Qualified Importer Program	*20*	*5,624*	*20*	*5,737*	*20*	*5,852*	---	*115*
Third Party Auditor Program	*1*	*755*	*1*	*771*	*1*	*787*	---	*16*
Outsourcing Facility	*5*	*1,613*	*5*	*1,646*	*5*	*1,679*	---	*33*
Over the Counter Monograph	---	*28,968*	---	*30,356*	---	*31,800*	---	*1,444*
Subtotal, Indefinite	**166**	**93,311**	**166**	**95,989**	**166**	**98,745**	**---**	**2,756**
Proposed								
Export Certification (Proposed)	---	---	---	---	---	*4,542*	---	*4,542*
Expand tobacco products (Proposed)	---	---	---	---	---	*100,000*	---	*100,000*
Subtotal, Proposed	**---**	**---**	**---**	**---**	**---**	***104,542***	**---**	***104,542***
Total User Fees	**8,132**	**2,885,048**	**8,301**	**3,128,632**	**8,354**	**3,278,167**	**53**	**149,535**
Total Budget Authority, Pre-Transfer	**10,175**	**3,366,933**	**10,353**	**3,592,938**	**10,762**	**3,964,816**	**409**	**371,878**
BA, S&E	*9,988*	*3,304,145*	*10,166*	*3,530,150*	*10,575*	*3,896,028*	*409*	*365,878*
BA, B&F	---	*12,788*	---	*12,788*	---	*18,788*	---	*6,000*
21st Century Cures	*187*	*50,000*	*187*	*50,000*	*187*	*50,000*	---	---
Total Program Level, Pre-Transfer	**18,307**	**6,251,981**	**18,654**	**6,721,570**	**19,116**	**7,242,983**	**462**	**521,413**
HHS OIG transfer (BA Only)	**---**	**-1,500**	**---**	**-1,500**	**---**	**-1,500**	**---**	**---**
Total Budget Authority, Post-Transfer	**10,175**	**3,365,433**	**10,353**	**3,591,438**	**10,762**	**3,963,316**	**409**	**371,878**
Total User Fees	**8,132**	**2,885,048**	**8,301**	**3,128,632**	**8,354**	**3,278,167**	**53**	**149,535**
Total Program Level, Post-Transfer	**18,307**	**6,250,481**	**18,654**	**6,720,070**	**19,116**	**7,241,483**	**462**	**521,413**
Pandemic Preparedness Mandatory via PHSSEF (non-add)	**---**	**---**	**---**	**---**	**---**	**670,000**	**---**	**670,000**
NEF	**---**	**81,200**	**---**	**109,070**	**---**	**62,600**	**---**	**-46,470**

*FY 2022 Final level reflects the Transfer notification #1 for Essential Services, Pay Increase Reallocation, and Animal Feed Ingredients. The $1M provided in FY 2022 for Animal Feed Ingredient Reviews is part of the $13M unrequested increases in FY 2022. This was appropriated to Foods Center instead of Animal Foods Center. The Transfer will move the $1M to Animal Foods Center. The reallocations included in this notification carried forward into FY 2023.

**The FY 2022 Final level includes Transfer notification #2 which reflects a $13.7M transfer from GSA Rent to Other Rent and Rent Related. This reallocation does not carry forward in FY 2023.

***FY 2023 Enacted 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.

****FY 2023 Enacted User Fee estimates reflect an updated allocation based on the target revenue in the October 2022 FRNs.

*****FY 2024 PB reflects FDARA Sec 905 UF/BA net zero realignment and a comparability adjustment for WCF new entrants.

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

*******The FY 2024 budget also provides $20 billion in mandatory funding across HHS for pandemic preparedness, which is reflected in the Public Health and Social Services Emergency Fund chapter. Of this total, FDA will receive $670 million.

Figure 8 - All-Purpose Table 6/6

BUDGET AUTHORITY CROSSWALK

(Dollars in Thousands)	FY 2023 Enacted		FY 2024 CJ							
			ORA Transfer to HQ/OGPS		FDARA Sec. 905 BA Shift		Comparability Adjustment		Infrastructure and B & F	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:										
Foods	**3,925**	**1,196,097**	**-25**	**-16,214**	**---**	**---**	**---**	**11,880**	**---**	**---**
Center	1,224	401,867	---	---	---	---	---	7,875	---	---
Field	2,701	794,230	-25	-16,214	---	---	---	4,005	---	---
Human Drugs	**2,162**	**760,494**	**-7**	**-3,630**	**---**	**-41,669**	**---**	**3,037**	**---**	**---**
Center	1,353	549,993	---	---	---	-39,667	---	2,688	---	---
Field	809	210,501	-7	-3,630	---	-2,002	---	349	---	---
Biologics	**831**	**271,515**	**-2**	**-968**	**---**	**-5,816**	**---**	**754**	**---**	**---**
Center	598	223,465	---	---	---	-5,761	---	652	---	---
Field	233	48,050	-2	-968	---	-55	---	102	---	---
Animal Drugs and Foods	**874**	**230,093**	**-3**	**-1,452**	**---**	**---**	**---**	**1,737**	**---**	**---**
Center	553	148,141	---	---	---	---	---	1,391	---	---
Field	321	81,952	-3	-1,452	---	---	---	346	---	---
Devices and Radiological Health	**1,538**	**449,297**	**-4**	**-1,936**	**---**	**-5,383**	**---**	**1,553**	**---**	**---**
Center	1,043	356,062	---	---	---	-5,320	---	923	---	---
Field	495	93,235	-4	-1,936	---	-63	---	630	---	---
National Center for Toxicological Research	**286**	**76,919**	**---**	**---**	**---**	**---**	**---**	**469**	**---**	**---**
FDA Headquarters	**550**	**224,940**	**41**	**24,200**	**---**	**---**	**---**	**-19,430**	**---**	**---**
FDA White Oak Complex	**---**	**48,414**	**---**	**---**	**---**	**4,084**	**---**	**---**	**---**	**626**
Other Rent and Rent Related	**---**	**106,095**	**---**	**---**	**---**	**48,784**	**---**	**---**	**---**	**12,374**
GSA Rental Payments	**---**	**166,286**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**-9,600**
Subtotal, Salaries and Expenses Account	**10,166**	**3,530,150**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**3,400**
Buildings and Facilities Account	**---**	**12,788**	**---**	**---**	**---**	**---**		**---**		**6,000**
Total Budget Authority, Pre-Transfer	**10,166**	**3,542,938**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**9,400**
Non-Field Activities	**5,607**	**1,981,387**	**41**	**24,200**	**---**	**-50,748**	**---**	**-5,432**	**---**	**---**
Field Activities	**4,559**	**1,227,968**	**-41**	**-24,200**	**---**	**-2,120**	**---**	**5,432**	**---**	**---**
Rent Activities, B&F, and White Oak	**---**	**333,583**	**---**	**---**	**---**	**52,868**	**---**	**---**	**---**	**9,400**
21st Century Cures	**187**	**50,000**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority with 21st Century Cures	**10,353**	**3,592,938**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**9,400**
HHS OIG transfer	**---**	**-1,500**								
Total Budget Authority, Post-Transfer	**10,353**	**3,591,438**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**9,400**

Figure 9 - Budget Authority Crosswalk 1/4

(Dollars in Thousands)	FY 2024 CJ															
	Enhancing Food Safety, Nutrition, and Cosmetics															
	New Era of Smarter Food Safety		Emerging Chemical and Toxicological Issues		Healthy and Safe Food for All		Food Supply Chain Continuity		Animal Food Safety Lifecycle		Nutrition and Labeling		Modernization of Cosmetics Implementation		Total Food Safety	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																
Foods	**22**	**27,442**	**8**	**5,000**	**154**	**64,000**	**2**	**2,000**	**---**	**---**	**19**	**12,000**	**6**	**2,500**	**211**	**112,942**
Center	19	22,193	8	5,000	79	40,985	2	2,000	---	---	19	12,000	6	2,500	133	84,678
Field	3	5,249	---	---	75	23,015	---	---	---	---	---	---	---	---	78	28,264
Human Drugs	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Center	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Biologics	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Center	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Animal Drugs and Foods	**34**	**8,128**	**---**	**---**	**---**	**---**	**---**	**---**	**21**	**5,181**	**---**	**---**	**---**	**---**	**55**	**13,309**
Center	34	8,128	---		---		---		16	3,775	---	---	---	---	50	11,903
Field	---	---	---	---	---	---	---	---	5	1,406	---		---	---	5	1,406
Devices and Radiological Health	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Center	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---	---
National Center for Toxicological Research	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
FDA Headquarters	**2**	**1,430**	**---**	**---**	**---**	**---**	**---**	**3,000**	**---**	**---**	**---**	**---**	**6**	**2,500**	**8**	**6,930**
FDA White Oak Complex	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Other Rent and Rent Related	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
GSA Rental Payments	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Subtotal, Salaries and Expenses Account	**58**	**37,000**	**8**	**5,000**	**154**	**64,000**	**2**	**5,000**	**21**	**5,181**	**19**	**12,000**	**12**	**5,000**	**274**	**133,181**
Buildings and Facilities Account	**---**	**---**									**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority, Pre-Transfer	**58**	**37,000**	**8**	**5,000**	**154**	**64,000**	**2**	**5,000**	**21**	**5,181**	**19**	**12,000**	**12**	**5,000**	**274**	**133,181**
Non-Field Activities	**55**	**31,751**	**8**	**5,000**	**79**	**40,985**	**2**	**5,000**	**16**	**3,775**	**19**	**12,000**	**12**	**5,000**	**191**	**103,511**
Field Activities	**3**	**5,249**	**---**	**---**	**75**	**23,015**	**---**	**---**	**5**	**1,406**	**---**	**---**	**---**	**---**	**83**	**29,670**
Rent Activities, B&F, and White Oak	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
21st Century Cures	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**
Total Budget Authority with 21st Century Cures	**58**	**37,000**	**8**	**5,000**	**154**	**64,000**	**2**	**5,000**	**21**	**5,181**	**19**	**12,000**	**12**	**5,000**	**274**	**133,181**
HHS OIG transfer																
Total Budget Authority, Post-Transfer	**58**	**37,000**	**8**	**5,000**	**154**	**64,000**	**2**	**5,000**	**21**	**5,181**	**19**	**12,000**	**12**	**5,000**	**274**	**133,181**

Figure 10 - Budget Authority Crosswalk 2/4

(Dollars in Thousands)	FY 2024 CJ													
	Advancing Safe & Effective Medical Products													
	Device Shortages and Supply Chain		Postmarket Safety Collaborative		Advancing the Goal of Ending the Opioid Crisis		Medical Product Safety Data Modernization		Act for ALS		Reigniting Cancer Moonshot		Total Medical Product Safety	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:														
Foods	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Center	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Human Drugs	---	---	**5**	**4,100**	**10**	**21,850**	---	---	**3**	**1,231**	---	---	**18**	**27,181**
Center	---	---	5	4,100	5	19,550	---	---	3	1,231	---	---	13	24,881
Field	---	---	---	---	5	2,300	---	---	---	---	---	---	5	2,300
Biologics	---	---	---	---	---	---	---	**276**	**2**	**530**	---	---	**2**	**806**
Center	---	---	---	---	---	---	---	276	2	530	---	---	2	806
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Animal Drugs and Foods	---	---	**10**	**3,000**	---	---	---	**1,739**	---	---	---	---	**10**	**4,739**
Center	---	---	10	3,000	---	---	---	1,739	---	---	---	---	10	4,739
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Devices and Radiological Health	**10**	**11,600**	---	**3,000**	**3**	**1,150**	---	**985**	**1**	**323**	---	---	**14**	**17,058**
Center	10	11,600	---	3,000	3	1,150	---	985	1	323	---	---	14	17,058
Field	---	---	---	---	---	---	---	---	---	---	---	---	---	---
National Center for Toxicological Research	---	---	---	---	---	---	---	---	---	---	---	---	---	---
FDA Headquarters	---	---	---	---	---	---	---	---	**2**	**416**	**35**	**48,000**	**37**	**48,416**
FDA White Oak Complex	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Other Rent and Rent Related	---	---	---	---	---	---	---	---	---	---	---	---	---	---
GSA Rental Payments	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Subtotal, Salaries and Expenses Account	**10**	**11,600**	**15**	**10,100**	**13**	**23,000**	---	**3,000**	**8**	**2,500**	**35**	**48,000**	**81**	**98,200**
Buildings and Facilities Account													---	---
Total Budget Authority, Pre-Transfer	**10**	**11,600**	**15**	**10,100**	**13**	**23,000**	---	**3,000**	**8**	**2,500**	**35**	**48,000**	**81**	**98,200**
Non-Field Activities	**10**	**11,600**	**15**	**10,100**	**8**	**20,700**	---	**3,000**	**8**	**2,500**	**35**	**48,000**	**76**	**95,900**
Field Activities	---	---	---	---	**5**	**2,300**	---	---	---	---	---	---	**5**	**2,300**
Rent Activities, B&F, and White Oak	---	---	---	---	---	---	---	---	---	---	---	---	---	---
21st Century Cures	---	---	---	---	---	---	---	---	---	---	---	---	---	---
Total Budget Authority with 21st Century Cures	**10**	**11,600**	**15**	**10,100**	**13**	**23,000**	---	**3,000**	**8**	**2,500**	**35**	**48,000**	**81**	**98,200**
HHS OIG transfer														
Total Budget Authority, Post-Transfer	**10**	**11,600**	**15**	**10,100**	**13**	**23,000**	---	**3,000**	**8**	**2,500**	**35**	**48,000**	**81**	**98,200**

Figure 11 - Budget Authority Crosswalk 3/4

(Dollars in Thousands)	FY 2024 CJ										FY 2024 President's Budget	
	Strengthening FDA's Public Health & Mission Support Capacity								Total Changes			
	Enterprise Data and IT Modernization		Public Health Employee Pay Costs		OC Regulatory and Mission Support		Total Crosscutting					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:												
Foods	**3**	**2,106**	**---**	**39,911**	**6**	**2,130**	**9**	**44,147**	**195**	**152,755**	**4,120**	**1,348,852**
Center	1	672	---	12,851	1	680	2	14,203	135	106,756	1,359	508,623
Field	2	1,434	---	27,060	5	1,450	7	29,944	60	45,999	2,761	840,229
Human Drugs	**4**	**3,562**	**---**	**22,776**	**7**	**3,695**	**11**	**30,033**	**22**	**14,952**	**2,184**	**775,446**
Center	3	3,156	---	15,722	5	3,267	8	22,145	21	10,047	1,374	560,040
Field	1	406	---	7,054	2	428	3	7,888	1	4,905	810	215,406
Biologics	**1**	**1,044**	**---**	**9,326**	**3**	**909**	**4**	**11,279**	**4**	**6,055**	**835**	**277,570**
Center	1	926	---	7,256	1	784	2	8,966	4	4,663	602	228,128
Field	---	118	---	2,070	2	125	2	2,313	---	1,392	233	49,442
Animal Drugs and Foods	**---**	**442**	**---**	**8,314**	**3**	**507**	**3**	**9,263**	**65**	**27,596**	**939**	**257,689**
Center	---	277	---	5,635	1	337	1	6,249	61	24,282	614	172,423
Field	---	165	---	2,679	2	170	2	3,014	4	3,314	325	85,266
Devices and Radiological Health	**1**	**1,342**	**---**	**14,788**	**5**	**1,271**	**6**	**17,401**	**16**	**28,693**	**1,554**	**477,990**
Center	1	1,083	---	10,141	3	1,005	4	12,229	18	24,890	1,061	380,952
Field	---	259	---	4,647	2	266	2	5,172	-2	3,803	493	97,038
National Center for Toxicological Research	**---**	**116**	**---**	**2,575**	**---**	**75**	**---**	**2,766**	**---**	**3,235**	**286**	**80,154**
FDA Headquarters	**2**	**1,388**	**---**	**7,607**	**19**	**7,213**	**21**	**16,208**	**107**	**76,324**	**657**	**301,264**
FDA White Oak Complex	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**4,710**	**---**	**53,124**
Other Rent and Rent Related	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**61,158**	**---**	**167,253**
GSA Rental Payments	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**-9,600**	**---**	**156,686**
Subtotal, Salaries and Expenses Account	**11**	**10,000**	**---**	**105,297**	**43**	**15,800**	**54**	**131,097**	**409**	**365,878**	**10,575**	**3,896,028**
Buildings and Facilities Account	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**6,000**	**---**	**18,788**
Total Budget Authority, Pre-Transfer	**11**	**10,000**	**---**	**105,297**	**43**	**15,800**	**54**	**131,097**	**409**	**371,878**	**10,575**	**3,914,816**
Non-Field Activities	**8**	**7,618**	**---**	**61,787**	**30**	**13,361**	**38**	**82,766**	**346**	**250,197**	**5,953**	**2,231,584**
Field Activities	**3**	**2,382**	**---**	**43,510**	**13**	**2,439**	**16**	**48,331**	**63**	**59,413**	**4,622**	**1,287,381**
Rent Activities, B&F, and White Oak	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**9,400**	**---**	**395,851**
21st Century Cures	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**---**	**187**	**50,000**
Total Budget Authority with 21st Century Cures	**11**	**10,000**	**---**	**105,297**	**43**	**15,800**	**54**	**131,097**	**409**	**371,878**	**10,762**	**3,964,816**
HHS OIG transfer							**---**		**---**	**---**	**---**	**-1,500**
Total Budget Authority, Post-Transfer	**11**	**10,000**	**---**	**105,297**	**43**	**15,800**	**54**	**131,097**	**409**	**371,878**	**10,762**	**3,963,316**

Figure 12 - Budget Authority Crosswalk 4/4

MAJOR ACTIVITIES TABLE

Major Activities																								
(Dollars in Thousands)	FY 2022 Final						FY 2023 Enacted						FY 2024 President's Budget						FY 2024 President's Budget +/- FY 2023 Enacted					
	Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total	
Programs	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**	**FTE**	**$000**
Budget Authority:																								
Foods	**3,879**	**1,131,670**	**---**	**---**	**3,879**	**1,131,670**	**3,925**	**1,196,097**	**---**	**---**	**3,925**	**1,196,097**	**4,120**	**1,348,852**	**---**	**---**	**4,120**	**1,348,852**	**195**	**152,755**	**---**	**---**	**195**	**152,755**
Center	1,187	367,174			1,187	367,174	1,224	401,867	---	---	1,224	401,867	1,359	508,623	---	---	1,359	508,623	135	106,756	---	---	135	106,756
Field	2,692	764,496			2,692	764,496	2,701	794,230	---	---	2,701	794,230	2,761	840,229	---	---	2,761	840,229	60	45,999	---	---	60	45,999
Human Drugs	**---**	**---**	**2,119**	**714,446**	**2,119**	**714,446**	**---**	**---**	**2,162**	**760,494**	**2,162**	**760,494**	**---**	**---**	**2,184**	**775,446**	**2,184**	**775,446**	**---**	**---**	**22**	**14,952**	**22**	**14,952**
Center			1,327	518,135	1,327	518,135	---	---	1,353	549,993	1,353	549,993	---	---	1,374	560,040	1,374	560,040	---	---	21	10,047	21	10,047
Field			792	196,311	792	196,311	---	---	809	210,501	809	210,501	---	---	810	215,406	810	215,406	---	---	1	4,905	1	4,905
Biologics	**---**	**---**	**824**	**259,953**	**824**	**259,953**	**---**	**---**	**831**	**271,515**	**831**	**271,515**	**---**	**---**	**835**	**277,570**	**835**	**277,570**	**---**	**---**	**4**	**6,055**	**4**	**6,055**
Center			595	215,127	595	215,127	---	---	598	223,465	598	223,465	---	---	602	228,128	602	228,128	---	---	4	4,663	4	4,663
Field			229	44,826	229	44,826	---	---	233	48,050	233	48,050	---	---	233	49,442	233	49,442	---	---	---	1,392	---	1,392
Animal Drugs and Foods	**444**	**106,071**	**397**	**96,464**	**841**	**202,535**	**454**	**120,808**	**420**	**109,285**	**874**	**230,093**	**508**	**138,038**	**431**	**119,651**	**939**	**257,689**	**54**	**17,230**	**11**	**10,366**	**65**	**27,596**
Center	147	36,583	383	93,528	530	130,111	148	42,095	405	106,046	553	148,141	198	56,076	416	116,347	614	172,423	50	13,981	11	10,301	61	24,282
Field	297	69,488	14	2,936	311	72,424	306	78,713	15	3,239	321	81,952	310	81,962	15	3,304	325	85,266	4	3,249	---	65	4	3,314
Devices and Radiological Health	**---**	**---**	**1,519**	**419,457**	**1,519**	**419,457**	**---**	**---**	**1,538**	**449,297**	**1,538**	**449,297**	**---**	**---**	**1,554**	**477,990**	**1,554**	**477,990**	**---**	**---**	**16**	**28,693**	**16**	**28,693**
Center			1,028	331,904	1,028	331,904	---	---	1,043	356,062	1,043	356,062	---	---	1,061	380,952	1,061	380,952	---	---	18	24,890	18	24,890
Field			491	87,553	491	87,553	---	---	495	93,235	495	93,235	---	---	493	97,038	493	97,038	---	---	-2	3,803	-2	3,803
National Center for Toxicological Research	**21**	**5,276**	**255**	**65,115**	**276**	**70,391**	**23**	**6,236**	**263**	**70,683**	**286**	**76,919**	**23**	**6,498**	**263**	**73,656**	**286**	**80,154**	**---**	**262**	**---**	**2,973**	**---**	**3,235**
FDA Headquarters	**184**	**59,121**	**346**	**127,860**	**530**	**205,981**	**192**	**65,635**	**358**	**140,305**	**550**	**224,940**	**221**	**79,246**	**436**	**203,018**	**657**	**301,264**	**29**	**13,611**	**78**	**62,713**	**107**	**76,324**
FDA White Oak Campus	**---**	**---**	**---**	**---**	**---**	**46,664**	**---**	**---**	**---**	**---**	**---**	**48,414**	**---**	**---**	**---**	**---**	**---**	**53,124**	**---**	**---**	**---**	**---**	**---**	**4,710**
Other Rent and Rent Related	**---**	**50,333**	**---**	**49,429**	**---**	**99,762**	**---**	**53,528**	**---**	**52,567**	**---**	**106,095**	**---**	**84,384**	**---**	**82,869**	**---**	**167,253**	**---**	**30,856**	**---**	**30,302**	**---**	**61,158**
GSA Rental Payments	**---**	**71,578**	**---**	**81,708**	**---**	**153,286**	**---**	**77,648**	**---**	**88,638**	**---**	**166,286**	**---**	**73,165**	**---**	**83,521**	**---**	**156,686**	**---**	**-4,483**	**---**	**-5,117**	**---**	**-9,600**
SUBTOTAL, BA Salaries and Expenses	**4,528**	**1,424,049**	**5,460**	**1,814,432**	**9,988**	**3,304,145**	**4,594**	**1,519,952**	**5,572**	**1,942,784**	**10,166**	**3,530,150**	**4,872**	**1,730,183**	**5,703**	**2,093,721**	**10,575**	**3,896,028**	**278**	**210,231**	**131**	**150,937**	**409**	**365,878**
Building and Facilities	**---**	**---**	**---**	**---**	**---**	**12,788**	**---**	**---**	**---**	**---**	**---**	**12,788**	**---**	**---**	**---**	**---**	**---**	**18,788**	**---**	**---**	**---**	**---**	**---**	**6,000**
Non-Field Activities	**1,539**	**468,154**	**3,934**	**1,351,669**	**5,473**	**1,838,823**	**1,587**	**515,833**	**4,020**	**1,446,554**	**5,607**	**1,981,387**	**1,801**	**650,443**	**4,152**	**1,562,141**	**5,953**	**2,231,584**	**214**	**134,610**	**132**	**115,587**	**346**	**250,197**
Field Activities	**2,989**	**833,984**	**1,526**	**331,626**	**4,515**	**1,165,610**	**3,007**	**872,943**	**1,552**	**355,025**	**4,559**	**1,227,968**	**3,071**	**922,191**	**1,551**	**365,190**	**4,622**	**1,287,381**	**64**	**49,248**	**-1**	**10,165**	**63**	**59,413**
White Oak, Rent Activities, and B&F	**---**	**121,911**	**---**	**131,137**	**---**	**312,500**	**---**	**131,176**	**---**	**141,205**	**---**	**333,583**	**---**	**157,549**	**---**	**166,390**	**---**	**395,851**	**---**	**26,373**	**---**	**25,185**	**---**	**62,268**
21st Century Cures	**---**	**---**	**187**	**50,000**	**187**	**50,000**	**---**	**---**	**187**	**50,000**	**187**	**50,000**	**---**	**---**	**187**	**50,000**	**187**	**50,000**	**---**	**---**	**---**	**---**	**---**	**---**
Total BA	**4,528**	**1,424,049**	**5,647**	**1,864,432**	**10,175**	**3,366,933**	**4,594**	**1,519,952**	**5,759**	**1,992,784**	**10,353**	**3,592,938**	**4,872**	**1,730,183**	**5,890**	**2,143,721**	**10,762**	**3,964,816**	**278**	**210,231**	**131**	**150,937**	**409**	**371,878**

Figure 13 - Major Activities Table 1/2

Major Activities

(Dollars in Thousands)	FY 2022 Final						FY 2023 Enacted						FY 2024 President's Budget						FY 2024 President's Budget +/- FY 2023 Enacted					
	Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total		Food Safety		Medical Product Safety and Availability		Total	
Total BA, Pre-Transfer	**4,528**	**1,424,049**	**5,647**	**1,864,432**	**10,175**	**3,366,933**	**4,594**	**1,519,952**	**5,759**	**1,992,784**	**10,353**	**3,592,938**	**4,872**	**1,730,183**	**5,890**	**2,143,721**	**10,762**	**3,964,816**	**278**	**210,231**	**131**	**150,937**	**409**	**371,878**
Total User Fees	**50**	**16,749**	**6,717**	**2,145,621**	**8,132**	**2,885,048**	**50**	**17,086**	**6,868**	**2,388,655**	**8,301**	**3,128,632**	**50**	**17,428**	**6,910**	**2,437,630**	**8,354**	**3,278,167**	**---**	**342**	**42**	**48,975**	**53**	**149,535**
Current Law																								
Prescription Drug (PDUFA)	---	---	3,708	1,200,129	3,708	1,200,129	---	---	3,708	1,310,319	**3,708**	**1,310,319**	---	---	3,708	1,336,525	**3,708**	**1,336,525**	---	---	---	26,206	---	**26,206**
Medical Device (MDUFA)	---	---	878	243,473	878	243,473	---	---	1,019	324,777	**1,019**	**324,777**	---	---	1,061	331,273	**1,061**	**331,273**	---	---	42	6,496	**42**	**6,496**
Generic Drug (GDUFA)	---	---	1,740	539,656	1,740	539,656	---	---	1,740	582,500	**1,740**	**582,500**	---	---	1,740	594,150	**1,740**	**594,150**	---	---	---	11,650	---	**11,650**
Biosimilars (BsUFA)	---	---	126	40,040	126	40,040	---	---	126	41,600	**126**	**41,600**	---	---	126	42,432	**126**	**42,432**	---	---	---	832	---	**832**
Animal Drug (ADUFA)	---	---	121	31,641	121	31,641	---	---	121	32,144	**121**	**32,144**	---	---	121	33,500	**121**	**33,500**	---	---	---	1,356	---	**1,356**
Animal Generic Drug (AGDUFA)	---	---	65	24,798	65	24,798	---	---	75	29,303	**75**	**29,303**	---	---	75	25,000	**75**	**25,000**	---	---	---	-4,303	---	**-4,303**
Family Smoking Prevention and Tobacco Control Act	---	---	---	---	1,328	712,000	---	---	---	---	**1,346**	**712,000**	---	---	---	---	**1,357**	**712,000**	---	---	---	---	**11**	**---**
Mammography Quality Standards Act (MQSA)	---	---	37	18,991	37	18,991	---	---	37	19,371	**37**	**19,371**	---	---	37	19,758	**37**	**19,758**	---	---	---	387	---	**387**
Color Certification	---	---	---	---	37	10,678	---	---	---	---	**37**	**10,891**	---	---	---	---	**37**	**11,109**	---	---	---	---	---	**218**
Export Certification	---	2,043	26	2,940	26	4,983	---	2,084	26	2,999	**26**	**5,083**	---	2,126	26	3,059	**26**	**5,185**	---	42	---	60	---	**102**
Priority Review Vouchers (PRV) Tropical Disease	---	---	---	2,608	---	2,608	---	---	---	2,660	**---**	**2,660**	---	---	---	2,713	**---**	**2,713**	---	---	---	53	---	**53**
Priority Review Vouchers (PRV) Pediatric Disease	---	---	11	8,156	11	8,156	---	---	11	8,320	**11**	**8,320**	---	---	11	8,486	**11**	**8,486**	---	---	---	166	---	**166**
Priority Review Vouchers (PRV) Medical Countermeasures			---	2,608	---	2,608			---	2,660	**---**	**2,660**			---	2,713	**---**	**2,713**	---	---	---	53	---	**53**
Food and Feed Recall	5	1,522	---	---	5	1,522	5	1,552	---	---	**5**	**1,552**	5	1,584	---	---	**5**	**1,584**	---	32	---	---	---	**32**
Food Reinspection	24	6,805	---	---	24	6,805	24	6,942	---	---	**24**	**6,942**	24	7,079	---	---	**24**	**7,079**	---	137	---	---	---	**137**
Voluntary Qualified Importer Program	20	5,624	---	---	20	5,624	20	5,737	---	---	**20**	**5,737**	20	5,852	---	---	**20**	**5,852**	---	115	---	---	---	**115**
Third Party Auditor Program	1	755	---	---	1	755	1	771	---	---	**1**	**771**	1	787	---	---	**1**	**787**	---	16	---	---	---	**16**
Outsourcing Facility			5	1,613	5	1,613			5	1,646	**5**	**1,646**			5	1,679	**5**	**1,679**	---	---	---	33	---	**33**
Over the Counter Monograph	---	---	---	28,968	---	28,968	---	---	---	30,356	**---**	**30,356**	---	---	---	31,800	**---**	**31,800**	---	---	---	1,444	---	**1,444**
Proposed					---	---					**---**	**---**					**---**	**---**	---	---	---	---	---	**---**
Export Certification (Proposed)	---	---	---	---	---	---	---	---	---	---	**---**	**---**	---	---	---	4,542	**---**	**4,542**	---	---	---	4,542	---	**4,542**
Expand Tobacco Products (Proposed)	---	---	---	---	---	---	---	---	---	---	**---**	**---**	---	---	---	---	**---**	**100,000**	---	---	---	---	---	**100,000**
Food and Feed additive user fee (Proposed)	---	---	---	---	---	---	---	---	---	---	**---**	**---**	---	---	---	---	**---**	**---**	---	---	---	---	---	**---**
Cosmetics (Proposed)	---	---	---	---	---	---	---	---	---	---	**---**	**---**	---	---	---	---	**---**	**---**	---	---	---	---	---	**---**
Total Program Level, Pre-Transfer	**4,578**	**1,440,798**	**12,364**	**4,010,053**	**18,307**	**6,251,981**	**4,644**	**1,537,038**	**12,627**	**4,381,439**	**18,654**	**6,721,570**	**4,922**	**1,747,611**	**12,800**	**4,581,351**	**19,116**	**7,242,983**	**278**	**210,573**	**173**	**199,912**	**462**	**521,413**
HHS OIG transfer	**---**	**---**	**---**	**---**	**---**	**-1,500**	**---**	**---**	**---**	**---**	**---**	**-1,500**	**---**	**---**	**---**	**---**	**---**	**-1,500**	**---**	**---**	**---**	**---**	**---**	**---**
Total BA, Post-Transfer	**4,528**	**1,424,049**	**5,647**	**1,864,432**	**10,175**	**3,365,433**	**4,594**	**1,519,952**	**5,759**	**1,992,784**	**10,353**	**3,591,438**	**4,872**	**1,730,183**	**5,890**	**2,143,721**	**10,762**	**3,963,316**	**278**	**210,231**	**131**	**150,937**	**409**	**371,878**
Total Program Level, Post-Transfer	**4,578**	**1,440,798**	**12,364**	**4,010,053**	**18,307**	**6,250,481**	**4,644**	**1,537,038**	**12,627**	**4,381,439**	**18,654**	**6,720,070**	**4,922**	**1,747,611**	**12,800**	**4,581,351**	**19,116**	**7,241,483**	**278**	**210,573**	**173**	**199,912**	**462**	**521,413**

*Total Budget Authority includes $10 million for the China Initiative and $7.5 million for Foreign High Risk Inspections. FDA White Oak Consolidation, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification User Fees are not included in Food Safety and Medical Product Safety and Availability activities. Medical Countermeasures are included in Medical Product Safety and Availability activities.

**Includes $1M reprogramming of the Cannabis funding in HQ. It will be designated as cross-cutting in order to better support FDA's ability to coordinate and oversee a regulatory area which impacts multiple types of products.

***Food Safety total is inclusive of Human Food, Animal Food, Nutrition, and Cosmetics.

Figure 14 - Major Activities 2/2

BUDGET EXHIBITS

COVID-19 SUPPLEMENTAL FUNDING

The COVID-19 pandemic has significantly impacted and dominated FDA's work and focus since early 2020. FDA proactively issued policies and guidance, as well as emergency use authorizations, to provide regulatory flexibility to respond to the pandemic and to help address supply chain vulnerabilities. FDA has made available safe and effective medical devices, therapeutics, and vaccines, including through human and animal drug approvals, to fulfill our responsibilities to ensure that safe and reliable medical products are available to the American public.

Since March 2020, FDA received $940.5 million in appropriations or allocations from the Coronavirus Preparedness and Response Supplemental (P.L. 116-123), the Coronavirus Aid, Relief, and Economic Security Act or CARES Act (P.L. 116-136), the Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139), the Consolidated Appropriations Act, 2021 (P.L. 116-260), and the American Rescue Plan (P.L. 117-2). The COVID-19 emergency supplemental resources supported FDA's ability to address the COVID-19 pandemic. FDA continues to actively assess the impact of new strains on approved and authorized products and continues to evaluate the impact each variant may have on the effectiveness of those medical products. FDA also continues to monitor the safety of COVID-19 products approved or authorized to treat and prevent COVID-19 through active and passive surveillance. FDA adapted operations as a result of COVID-19 and SARS-CoV-2 variants and will continue to address the challenges of this unprecedented public health emergency. FDA continues to work tirelessly to respond to the COVID-19 public health emergency, and it is critical that the Agency learns from successes and the challenges to best improve operations.

Food and Drug Administration
COVID-19 Supplemental Funding
(Dollars in thousands)

COVID-19 Supplemental	Appropriation
Coronavirus Preparedness and Response Supplemental Appropriations Act (P.L. 116-123)	61,000
Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136)	80,000
Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139)/1	22,000
Consolidated Appropriations Act (P.L. 116-260)	55,000
American Rescue Plan Act of 2021, (P.L. 117-2)/2	722,500
Total	**940,500**

1/Provided via direct transfer from HHS.
2/PL 117-2 provided $500M to FDA, and $222.5M was provided via an IDDA from HHS.

Figure 15 - COVID-19 Supplemental Funding

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**[**$6,562,793,000**]***$6,912,408,000: Provided,* That of the amount provided under this heading, **[**$1,310,319,000**]***$1,336,525,000* 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; **[**$324,777,000**]***$331,273,000* 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; **[**$582,500,000**]***$594,150,000* 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; **[**$41,600,000**]***$42,432,000* 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**[**; $32,144,000 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; $29,303,000 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, *and* biosimilar biological product user **[**fees, animal drug user fees, and generic new animal drug user**]** fees that exceed the respective fiscal year **[**2023**]** *2024* 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, *and* biosimilar biological product**[,** animal drug, and generic new animal drug**]** assessments for fiscal year **[**2023**]** *2024*, including any such fees collected prior to fiscal year **[**2023**]** *2024* but credited for fiscal year **[**2023**]** *2024*, shall be subject to the fiscal year **[**2023**]** *2024* limitations: Provided further, That the Secretary may accept payment during fiscal year 2023 of user fees specified under this heading and authorized for fiscal year **[**2024**]** *2025*, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year **[**2024**]** *2025* for which the Secretary accepts payment in fiscal year **[**2023**]** *2024* 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) **[**$1,196,097,000**]***$1,348,852,000* shall be for the Center for Food Safety and Applied Nutrition and related field activities in the Office of Regulatory Affairs, of which no less than $15,000,000 shall be used for inspections of foreign seafood manufacturers and field

examinations of imported seafood; (2) **[**$2,289,290,000**]***$2,380,689,000* shall be for the Center for Drug Evaluation and Research and related field activities in the Office of Regulatory Affairs, of which no less than $10,000,000 shall be for pilots to increase unannounced foreign inspections and shall remain available until expended; (3) **[**$489,594,000**]***$509,255,000* shall be for the Center for Biologics Evaluation and Research and for related field activities in the Office of Regulatory Affairs; (4) **[**$287,339,000**]***$257,689,000* shall be for the Center for Veterinary Medicine and for related field activities in the Office of Regulatory Affairs; (5) **[**$736,359,000**]***$772,179,000* shall be for the Center for Devices and Radiological Health and for related field activities in the Office of Regulatory Affairs; (6) **[**$76,919,000**]***$80,154,000* shall be for the National Center for Toxicological Research; (7) **[**$677,165,000**]***$679,965,000* shall be for the Center for Tobacco Products and for related field activities in the Office of Regulatory Affairs; (8) **[**$214,082,000**]***$229,270,000* shall be for Rent and Related activities, of which **[**$55,893,000**]***$57,037,000* is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; (9**) [**$236,166,000**]***$233,810,000* shall be for payments to the General Services Administration for rent; and (10) **[**$359,782,000**]***$420,545,000* 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 **[**with the prior approval of**]** *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.

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**]***$18,788,000* to remain available until expended.

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'', $50,000,000, 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.

In addition, contingent upon the enactment of authorizing legislation, the Secretary shall charge a fee for animal drug review activities and generic new animal drug review activities: Provided, That fees of $32,786,000 for animal drug reviews shall be credited to this account and remain available until expended; and fees of $29,889,000 for generic new animal drug reviews 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 animal drug user fees and generic new animal drug user fees that exceed the respective fiscal year 2024 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from animal drug reviews and generic new animal drugs reviews for fiscal year 2024 received during fiscal year 2024, including any such fees assessed prior to fiscal year 2024 but credited for fiscal year 2024, shall be subject to the fiscal year 2024 limitations: Provided further, That the Secretary may accept payment during fiscal year 2024 of user fees specified in this paragraph and authorized for fiscal year 2025, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year 2025 for which the Secretary accepts payment in fiscal year 2024 shall not be included in amounts in this paragraph.

APPROPRIATION LANGUAGE ANALYSIS

Language Provision	Explanation
Animal Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for animal drugs. The additional resources are estimated at $29,678,000. This will support the FDA's responsibilities to ensure that new animal drug products are safe and effective for animals, as well as ensuring the safety of food from treated animals.
Animal Generic Drug User Fee	The Administration will propose legislation to allow FDA to collect fees for generic new animal drugs. The additional resources are estimated at $28,010,000. This will enhance the performance of the generic new animal drugs review process and enable the FDA to more efficiently ensure that generic new animal drug products are safe and effective.
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

(dollars in thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
General Fund Discretionary Appropriation:			
Appropriation	3,365,433	3,591,438	3,963,316
Total Discretionary Appropriation	**3,365,433**	**3,591,438**	**3,963,316**
Mandatory Appropriation:			
CRADA	2,000	2,000	2,000
American Rescue Plan Act of 2021 (P.L. 117-2)	222,500	---	---
Total Mandatory Appropriation	**224,500**	**2,000**	**2,000**
Offsetting Collections:			
Non-Federal Sources:	2,885,048	3,128,632	3,278,167
Total Offsetting Collections			
Total Obligations	**3,589,933**	**3,593,438**	**3,965,316**

*FY 2022, FY 2023 and FY 2024 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 16 - Amounts Available for Obligation

SUMMARY OF CHANGES

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

FY 2023 Enacted	
Total estimated budget authority	$3,591.438
(Obligations)	
FY 2024 President's Budget	
Total estimated budget authority	$3,963.316
(Obligations)	
Net Change	+$371.878

	FY 2023 Enacted		FY 2024 President's Budget 1/		FY 2024 +/- FY 2023	
	FTE	BA	FTE	BA	FTE	BA
Increases:						
Built-in:						
Commissioned corps pay increase	--	--	--	$5.755	--	+$5.755
Civilian pay increase	--	--	--	$99.542	--	+$99.542
Subtotal, Built-in Increases	**--**	**--**	**--**	**$105.297**	**--**	**+$105.297**
Infrastructure (WO & OR&RR) and B&F	--	$167.297	--	$186.297	--	+$19.000
Food Safety						
New Era of Smarter Food Safety	--	$20.150		$57.150	--	+$37.000
Emerging Chemical and Toxicological Issues	--	$15.000		$20.000	--	+$5.000
Healthy and Safe Food for All	--	--		$64.000	--	+$64.000
Food Suppy Chain Continuity				$5.000		+$5.000
Animal Food Safety Lifecycle	--	$13.775		$18.956	--	+$5.181
White House Nutrition Commitment and Food Labeling	--	--		$12.000	--	+$12.000
Modernization of Cosmetics Implimentation	--	--		$5.000	--	+$5.000
Medical Product Safety					--	--
Shortages & Supply Chain	--	$10.000		$21.600	--	+$11.600
Drug Safety Surveillance and Oversight	--	$1.500		$5.600	--	+$4.100
Strengthening FDA Postmarket Safety Collaborative	--	$25.200		$31.200	--	+$6.000
Advancing the Goal of Ending the Opioid Crisis		$79.500		$102.500	--	+$23.000
DMET Medical Product Safety	--	$44.000		$47.000	--	+$3.000
ACT for ALS	--	$5.000		$7.500	--	+$2.500
Cancer Moonshot	--	$2.000		$50.000	--	+$48.000
Crosscutting						
DMET Enterprise -Wide	--	$18.000		$28.000	--	+$10.000
OC Regulatory and Mission Support	--	$21.530		$37.330	--	+$15.800
Subtotal, Program Increases	**--**	**$422.952**	**--**	**$699.133**	**--**	**+$276.181**
Total Increases	**--**	**$422.952**	**--**	**$804.430**	**--**	**+$381.478**
Decreases:						
Infrastructure (GSA Rent)	--	$166.286	--	$156.686	--	-$9.600
	--	--	--	--	--	--
Subtotal, Program Decreases	**--**	**$166.286**	**--**	**$156.686**	**--**	**-$9.600**
Total Decreases	**--**	**$166.286**	**--**	**$156.686**	**--**	**-$9.600**
Net Change	**--**	**$589.238**	**--**	**$961.116**	**--**	**+$371.878**

1/ The FY 2024 President's Budget also includes $149.5 million in user fee increases. Within this amount, $100.0 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 Enacted and FY 2024 PB reflect $1.5 million transfer to HHS Office of the Inspector General to support oversight of FDA's expanded authorities,

Figure 17 - Summary of Changes

APPROPRIATIONS HISTORY

Salaries and Expenses

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation*:				
FY 2015 1/	4,689,706,000	4,428,900,000	4,443,356,000	4,443,356,000
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	7,002,708,000	---	---	---

* 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 and $50 million for FY 2024.

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 18 - S & E Appropriations History

Buildings and Facilities

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation:				
FY 2015	8,788,000	8,788,000	8,788,000	8,788,000
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			

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

Figure 19 – B & F Appropriations History

BUDGET AUTHORITY BY ACTIVITY

(dollars in thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget
Salaries and Expenses Account:			
Foods	**1,131,670**	**1,196,097**	**1,348,852**
Center	367,174	401,867	508,623
Field	764,496	794,230	840,229
Human Drugs	**714,446**	**760,494**	**775,446**
Center	518,135	549,993	560,040
Field	196,311	210,501	215,406
Biologics	**259,953**	**271,515**	**277,570**
Center	215,127	223,465	228,128
Field	44,826	48,050	49,442
Animal Drugs and Feeds	**202,535**	**230,093**	**257,689**
Center	130,111	148,141	172,423
Field	72,424	81,952	85,266
Devices and Radiological Health	**419,457**	**449,297**	**477,990**
Center	331,904	356,062	380,952
Field	87,553	93,235	97,038
National Center for Toxicological Research	**70,391**	**76,919**	**80,154**
FDA Headquarters	**205,981**	**224,940**	**301,264**
FDA White Oak Consolidation	**46,664**	**48,414**	**53,124**
Other Rent and Rent Related	**99,762**	**106,095**	**167,253**
GSA Rental Payments	**153,286**	**166,286**	**156,686**
Subtotal, Salaries and Expenses Account	**3,304,145**	**3,530,150**	**3,896,028**
21st Century Cures	**50,000**	**50,000**	**50,000**
Buildings and Facilities Account	**12,788**	**12,788**	**18,788**
Total Budget Authority	**3,366,933**	**3,592,938**	**3,964,816**
HHS OIG Transfer	**-1,500**	**-1,500**	**-1,500**
Total Budget Authority, Post-Transfer	**3,365,433**	**3,591,438**	**3,963,316**
FTE	**10,175**	**10,353**	**10,732**

* FTE figures do not include an estimated 82 reimbursable, 2 FOIA and 47 PEPFAR, 1 IDDA and 129 COVID Supplemental.

Figure 20 – FDA Budget Authority by Activity

LEGISLATIVE PROPOSALS

LEGISLATIVE PROPOSALS

Enhance Authorities Regarding 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. Currently, if multiple sponsors are marketing an animal drug or class of drugs with similar safety risks, the process of negotiating changes in labeling or ensuring implementation of other voluntary, post-approval actions to mitigate risks has been lengthy and created an uneven playing field as sponsors of similar drugs agree to different labeling changes on different timelines, resulting in inconsistent labeling information.

Change in Agency Regulatory Oversight Responsibility for Certain 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.

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

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. 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, not only for requests for Emergency Use Authorization (EUA) during the COVID-19 pandemic, but also for premarket submissions generally and 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 believes these new or clarified authorities would encourage 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, improving the reliability of their data. 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.

Explicitly Address Generic Drug-Device Combination Products in the FD&C Act

Section 505(j) of the FD&C Act does not explicitly address abbreviated new drug applications (ANDAs) for drug-device combination products, and certain statutory provisions in this section – which was established nearly 40 years ago at a time when most products were simpler dosage forms – 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, but which are not submitted as combination products. Among other things, 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.

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.

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. Without this change, FDA expects that the Federal Circuit's GSK v. Teva decision could significantly impact the timely availability of generic drugs.

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.

Enhancing FDA's Authority to Better Protect Infants and Young Children

FDA is seeking to amend the FD&C Act to grant FDA new authority to establish binding contamination limits in foods, including those consumed by infants and young children, via an administrative order process. Under current law, FDA has limited tools to help reduce exposure to toxic elements in the food supply. This new authority to allow FDA to establish contamination limits in foods, including those consumed by infants and young children, via the administrative order process would improve the efficiency, timeliness, and predictability of issuing binding limits to reduce exposure to toxic elements by these vulnerable populations, and updating limits as new scientific information becomes available.

Product Testing Requirements for Foods Marketed for Consumption by Infants and Young Children

Under current law, industry is not required to test ingredients or final products marketed for consumption by infants and young children, which would help assess levels of toxic elements in such foods. FDA is seeking to amend the FD&C Act to: (1) require industry to conduct toxic element testing of final products marketed for consumption by infants and young children and maintain such records of these testing results for FDA inspection; and (2) provide FDA with new authority to remotely access records of these test results and to review these test results whenever necessary. This new authority would help FDA understand levels of toxic elements in such

products, allow FDA to monitor industry progress in reducing levels of these toxic elements over time, and identify where FDA should devote more time and resources to better protect infants and young children. Additionally, FDA seeks new authority to require firms that manufacture foods marketed for consumption by infants and young children to (1) under specified circumstances, notify FDA of anticipated significant interruptions in the supply of such products; (2) report final product positive test results for relevant pathogens; and (3) conduct more frequent environmental monitoring in their facilities to identify relevant pathogens and maintain the results of such testing for FDA inspection, either in person or remotely.

Modernization of Tobacco User Fees Framework

The Federal Food, Drug, & Cosmetic (FD&C) Act, Section 919, 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. Section 919 also authorizes the total amount of tobacco user fees FDA must assess and collect each year. However, because electronic nicotine delivery systems (ENDS) were a relatively new product category when the FD&C Act was amended to give FDA authority to regulate tobacco products in 2009, the budgets established by Congress under Section 919 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 pre-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 efforts to reduce youth initiation through enforcement and compliance efforts, and divert funds from efforts related to smoked and smokeless tobacco products. This proposal seeks 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 $100 million; and index all future collections to inflation.

Amend the 180-Day Exclusivity Provisions to Encourage Timely Marketing of First Generics

FDA is proposing that the FD&C Act be revised to specify that 180-day patent challenge exclusivity for generic drugs does not block approval of subsequent applications from other generic drug manufacturers until a first applicant begins commercially marketing the drug; this revision should ensure that the exclusivity period lasts 180 days (i.e., from the date of first commercial marketing by a first applicant until 180 days later) rather than for multiple years, as can occur under current law (i.e., while the first applicant is eligible for 180-day exclusivity prior to commercial marketing in addition to the 180-day period itself). 180-day patent challenge exclusivity is intended to provide an incentive and a reward to the first generic drug applicant(s) to submit a substantially complete application with a certification that a patent listed for its reference listed drug is invalid, unenforceable or not infringed by the ANDA, and thus expose themselves to the risk of patent litigation. Forfeiture provisions, under which a first applicant

may lose its eligibility for this exclusivity, also seek to motivate first applicants to begin marketing quickly in order to reap the benefits of this marketing exclusivity. In practice, however, the framework has not been operating to encourage early generic entry. First applicants often "park" their eligibility for this exclusivity either by declining to begin marketing their product for extended periods of time after ANDA approval, or by delaying receipt of final approval of their ANDAs for extended periods of time, while avoiding a forfeiture. FDA's proposal would substantially increase the likelihood that generic versions of patent-protected drugs will come into the market in a timely fashion, and that multiple versions of generic products will be approved quickly (leading to significant cost savings).

Authority to Require Destruction of Imported Products that Present a Significant Public Health Concern

FDA seeks 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, an FDA violation 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.

Mandatory Recall Authority for All 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. 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. Under current law, 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.

Modernizing Dietary Supplement Health and Education Act (DSHEA)

Since the Dietary Supplement Health and Education Act of 1994 (DSHEA) was enacted almost 30 years ago, the dietary supplement market in the U.S. has grown from approximately 4,000

products to more than 95,000 products. FDA is seeking to modernize DSHEA to provide for a 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, with information to include 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.

Require Full Ingredient Disclosure for Drugs to Promote Generic Competition

FDA is seeking an amendment to the 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. 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. 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.

PANDEMIC AND ALL HAZARDS PREPAREDNESS ACT PROPOSALS

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. 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). 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 have occurred during the COVID-19 public health emergency for certain drugs needed to treat hospitalized patients.

Site Master Files for Drug Manufacturing Facilities

FDA seeks to amend the FD&C Act to explicitly require facilities at which human drugs (including both application and non-application products, and drugs compounded under Section 503B and biological products subject to the Public Health Service Act that also meet the definitions of drugs 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 the

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 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.

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 time to use a risk-based approach to determine if an inspection of the manufacturing facilities is necessary before the drug can be 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 feasible opportunity to inspect the manufacturing facilities before such products are 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 an 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.

Preventing Food Shortages

FDA is seeking authority to require firms to provide shortage notification for FDA-designated categories of food during a declared public health emergency. The recent COVID-19 pandemic has 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.

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 proposes to amend the Federal Food, Drug, and Cosmetic Act (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 by preempting any and all related state, local, or territorial disclosure laws in order to keep confidential non-public information provided by FDA (such as confidential commercial information). This proposal would advance an integrated food safety system and more effectively leverage the oversight capabilities and resources of FDA's state regulatory partners to allow for expanded mutual reliance related activities and other partnerships. The limitations on sharing all 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.

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

FDA's authority to conduct remote regulatory assessments 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 currently lacks authority to require any establishment to participate in remote interactive evaluations. The agency relies on voluntary participation for remote regulatory assessments of non-drug establishments but reliance on voluntary requests is not sufficient to achieve effective and efficient oversight, as firms can refuse to provide records or other information in advance of or in lieu of an inspection or to participate in remote regulatory assessments. This proposal would 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 Federal Food, Drug, and Cosmetic Act (FD&C Act) to explicitly include food, tobacco product, and cosmetic establishments. Additionally, this proposal would add explicit authority to conduct remote regulatory assessments with 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, by allowing FDA 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, and by allowing the FDA to assess conditions at a facility without going onsite when an in-person visit is not feasible or deemed necessary by FDA. For example, during a recent recall of infant formula, FDA has found that the inability to remotely request records delayed FDA's response to complaints about adulterated products.

Lengthen Expiration Dates to Mitigate Critical Drug Shortage

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 an applicant 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 an applicant fails to comply.

Device Shortages

Under the CARES Act, FDA received new authority relating to device shortages codified in section 506J of the FD&C Act. As of December 2022, we have received over 455 potential and actual shortage signals, which translates to hundreds of thousands of device units that have been in shortage. We used the information we collected under these new authorities to help mitigate approximately 350 of the 455 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 public health emergency (PHE), which means it will cease when the COVID-19 PHE ends in May 2023. However, shortages of critical medical devices will persist beyond the end of the COVID-19 PHE, 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 fiscal year (FY) 2023 Consolidated Appropriations Act (FY23 Omnibus) 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 ensure resiliency and mitigate future supply chain disruptions.

Require Labeling to include the Original Manufacturer and Supply Chain Information

FDA proposes amending 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 proposes amending 502 to deem finished drug products misbranded if the original manufacturer of the API isn't included on the finished drug product label or if certain additional supply chain information is not included in the broader finished drug product labeling. 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 that is found to be adulterated or misbranded and take appropriate action to address poor quality products from circulation.

Enhanced Drug Manufacturing Amount Information and Reporting

FDA is seeking to enhance the manufacturing volume information required to be reported under Section 510(j)(3) of the FD&C Act to expressly require registrants to provide data identifying the suppliers they relied on to manufacture the listed drug and the extent of such reliance. The Coronavirus Aid, Relief, and Economic Security Act (CARES Act), added section 510(j)(3) to the FD&C Act which requires drug manufacturers registered under section 510 of 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. Specifically, the information required to be submitted under section 510(j)(3) of the FD&C Act is insufficient to help FDA understand which suppliers registrants are relying upon and how reliant they are on them. 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 provided to FDA under section 510(j) and, for application products, the approved applications.

Emerging Pathogens Preparedness Program

FDA proposes to create a specialized program within the Center for Biologics Evaluation and Research (CBER) to defend against emerging pathogens so the Agency is better positioned to respond to identified threats of concern and focus experienced resources to work quickly on medical countermeasure development to address these concerns. The program would enhance regulatory capabilities and readiness to respond to emerging pathogens, ensure blood safety and availability, and expeditiously review new vaccines, new uses of existing vaccines and other medical products. In consultation with Health and Human Services partners, the program would: provide recommendations and guidance to developers of vaccines and other medical products and relevant federal partners; use real-world data or real-world evidence to study the safety and effectiveness of products for addressing biological incidents and identify which products may be best suited for specific pathogens or for use in different populations; and facilitate product development including advances in manufacturing. It would also support scientific research within CBER that contributes to development and review of biological products to counter biological incidents and emerging pathogens. The program would also maintain and build on enhancements to FDA's post-marketing active and passive safety and effectiveness surveillance programs.

NARRATIVE BY ACTIVITY

FOODS

PURPOSE STATEMENT

The purpose of the Foods Program is to protect and promote 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 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Foods	**1,087,215**	**1,099,001**	**1,143,206**	**1,207,864**	**1,360,855**	**152,991**
Budget Authority	***1,087,215***	***1,098,973***	***1,131,670***	***1,196,097***	***1,348,852***	***152,755***
User Fees	***---***	***28***	***11,536***	***11,767***	***12,003***	***236***
Center	334,966	343,289	368,057	402,768	509,542	106,774
Budget Authority	334,966	343,289	367,174	401,867	508,623	106,756
User Fees	---	---	883	901	919	18
Field	752,249	755,712	775,149	805,096	851,313	46,217
Budget Authority	752,249	755,684	764,496	794,230	840,229	45,999
User Fees	---	28	10,653	10,866	11,084	218
FTE	**3,816**	**4,037**	**3,923**	**3,969**	**4,164**	**195**

Figure 21 – Foods Funding History Table

The FY 2024 President's Budget for the Foods Program is $1,360,855,000 of which $1,348,852,000 is budget authority and $12,003,000 is user fees. The budget authority increases by $152,755,000 compared to the FY 2023 Enacted Budget. User Fees increase by $236,000 The Center for Food Safety and Applied Nutrition (CFSAN) amount in the request is $509,542,000. The Office of Regulatory Affairs (ORA) amount is $851,313,000.

The FY 2024 Budget makes significant investments in FDA's CFSAN. Despite CFSAN's mandate to oversee nearly 80% of food, all cosmetics, and all dietary supplements sold in the United States, the Center's funding has failed to keep up with dramatic growth in the industries it oversees. In contrast, prior to the 1992 passage of the Prescription Drug and User Fee Act, FDA's food and drug programs were a similar size. At present, FDA's drug program is double its

food oversight, and CDER is five times larger than CFSAN. This funding shortfall means CFSAN's operational capacity has not grown to meet 21st century challenges or stay current with evolving industry and food production practices.

Most of the additional funding will be utilized to make progress towards right sizing CFSAN and modernizing its work. 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. This will include modernizing oversight of infant formula, empowering consumers to make healthier food choices, reducing exposure to toxic chemicals, implementing new regulatory authorities for cosmetics, and strengthening the food safety system with data-driven approaches.

BUDGET AUTHORITY

FY 2024 President's Budget: Foods *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Enacted	**401,867**	**794,230**	**1,196,097**
FY 2024 Budget Authority Changes	**106,756**	**45,999**	**152,755**
Enhancing Food Safety, Nutrition & Cosmetics	**84,678**	**28,264**	**112,942**
New Era of Smarter Food Safety	22,193	5,249	27,442
Emerging Chemical and Toxicological Issues	5,000	-	5,000
Healthy and Safe Food for All	40,985	23,015	64,000
Food Supply Chain Continuity	2,000	-	2,000
Nutrition and Labeling	12,000	-	12,000
Modernization of Cosmetics Implementation	2,500	-	2,500
Investing in Core Operations - Crosscutting	**14,203**	**29,944**	**44,147**
Enterprise Data and IT Modernization	672	1,434	2,106
Public Health Employee Pay Costs	12,851	27,060	39,911
OC Regulatory and Mission Support	680	1,450	2,130
Other Adjustments	**7,875**	**(12,209)**	**(4,334)**
ORA Transfer to HQ/OGPS	-	(16,214)	(16,214)
Comparability Adjustment	7,875	4,005	11,880
FY 2024 Budget Net Total: Foods	**508,623**	**840,229**	**1,348,852**

Figure 22 - Foods Budget Authority

Food Safety: +$112.9 million / 211 FTE

New Era of Smarter Food Safety: +$27.4 million / 22 FTE

Center: +$22.2 million / 19 FTE

Field: +$5.2 million / 3 FTE

The FY 2024 Budget provides $37.0 million for the New Era of Smarter Food Safety, including an increase of $27.4 million for Center and Field activities. The Budget builds on the funding requested in the FY 2023 Budget to continue progress towards the goals of the New Era of Smarter Food Safety.

In order to better prevent foodborne illness, data-driven approaches that build upon FSMA's prevention-based framework are needed to improve predictive analytics capabilities and ultimately strengthen the food safety system. Funding will enable FDA to aggressively investigate foodborne illness outbreaks using tools of root cause analysis that will inform prevention strategies for those implicated food categories. These strategies will be the public facing roadmap for how all stakeholders, from industry, international partners, federal, State, Local, Tribal, and Territorial governments, and consumers can prevent foodborne illness from these foods. Prevention strategies targeting powdered infant formula, onions, leafy greens, Hispanic Style Cheese, tahini and other higher risk food categories will be built and executed with stakeholders. Advances in genomics and high-speed computing have greatly enhanced disease attribution capabilities leading to increased ability for FDA to detect repeat incidents of foodborne illness (e.g., pathogen and commodity pairs). These prevention strategies, when informed by root cause analysis will enable the agency to drive preventive measures with stakeholders that focus on the behaviors, practices, or ecological drivers responsible for foodborne illness in these categories.

Additional funding would also strengthen FDA's data access and analysis capabilities. FDA will foster increased access to external sources of high-quality data through data trusts and development of data sharing platforms that are key in prioritizing our efforts to those concerns with the greatest public health impact. Massive amounts of information are generated in the growth, harvest, transportation, manufacturing, and distribution of foods but these data systems are siloed preventing the generation of insights of how and when the food system is vulnerable to contamination. Most foodborne illness outbreaks are occurring in produce which is highly susceptible to contamination from the environment. The investment in data systems that collate the antecedents of contamination such as rain, temperature, winds, infestation, etc. around the growing regions will enable the agency and stakeholders to better understand vulnerability and preventive measures.

FDA will also promote and support development of low-cost, user-friendly mobile applications (e.g. cell phone apps) that encourage digitization of data (e.g., boat captain on the water, farmer in the field) thereby broadening public and private access to data that can be used to visualize changing factors that may impact local and global food systems in real-time. Within that single image taken of food at harvest are time and location data that, when layered with product safety data (e.g. time and temperature), will enable both the rapid identification and location of unsafe food as well as the conditions during harvest and transportation that may have led to the contamination. These location and temporal insights are critical to understanding the conditions that led to contamination and the identification of preventive measures.

FDA has been using genomic technology for foodborne pathogen surveillance since 2013, focusing on surveillance of food and environmental sample sources that are so often the cause of foodborne outbreaks. GenomeTrakr's core function for genomic surveillance and genomic epidemiology of foodborne pathogens enables FDA to conduct timelier trackback and root cause analyses of foodborne outbreaks. Data collected through GenomeTrakr can be used to develop commodity-specific prevention plans for human food, for example, to address food safety issues through targeted initiatives directed at specific risk/commodity combinations, such as Shiga Toxin-producing E.coli and Leafy Greens.

Funding in the FY 2024 Budget will be used to create a formal genomic epidemiology program within the agency, providing staff and accountability needed for future data expansion through establishment of baseline surveillance and laboratory presence to level the playing field in all l 50 states and territories and ensure that all state laboratories have the same tools to support food safety. FDA will recruit data science experts and further assimilate internal and external data sources to better leverage new data streams generated by modern food safety approaches and new tools for rapidly analyzing big data. FDA will establish public-facing dashboards for real-time summary and synthesis of GenomeTrakr data for better public communication of the resources and program. Growing FDA's genomic epidemiology resources, alongside our USG counterparts, will allow FDA to link human illness more quickly to environmental reservoirs, enabling quicker product removal from the marketplace, reducing the impact on industry, while at the same time leading to further reductions in human illness.

Healthy and Safe Food for All: +$64.0 million / 154 FTE

Center: +$41.0 million / 79 FTE

Field: +$23.0 million / 75 FTE

The FY 2024 Budget provides an increase of $64.0 million above FY 2023 Enacted for Healthy and Safe Food for All, for a total of $87.0 million including $41.0 million to CFSAN and $23.0 million to ORA. The FY 2024 Budget will help to modernize oversight of infant formula, empower consumers to make healthier food choices, reduce exposure to toxic chemicals in the food supply, and provide resources to update the agency's approach to assessing chemicals and food ingredients.

The voluntary shutdown of Abbott Nutrition's facility in Sturgis, Michigan and the related recall have created hardships obtaining infant formula, particularly given the overall strain on supply chains due to the COVID-19 pandemic that continue to impact infant formula availability. The Agency is working to do everything within its authority to address and alleviate supply issues while ensuring consumer safety. This includes working with industry to increase production; exercising flexibility with respect to various requirements for both domestically-produced and imported formulas and setting up a transition pathway for manufacturers to bring certain of these products into full compliance with all US regulatory requirements and so gain permanent entry to the U.S. marketplace; and working with Abbot Nutrition to ensure the Sturgis, Michigan facility is producing infant formula in a safe and sanitary manner.

By building on investments included in the FY 2023 Omnibus, FDA will improve oversight of infant formula and build a much more robust program that is poised to meet current and future challenges. Proposed enhancements include increasing infant formula pre-market notification review capacity; hiring additional staff to review Generally Recognized as Safe (GRAS)

notifications for infant formula ingredients; enhancing surveillance and monitoring of adverse events; and refining laboratory methods for detecting Cronobacter sakazakii. FDA will further modernize infant formula oversight by hiring additional experts to stay current on innovations in infant formula ingredients and production technology and to ensure full, fair, and timely review of all pre-market notifications and adverse event reports, as well as the rapidly evolving science of infant nutrition. Funds will also support the immediate review of all inspection findings and initiation of a rapid response when violations are identified. These actions will ensure the maximum effectiveness of FDA's programs and policies related to infant formula and medical food complaints, illnesses, and recalls.

Supporting patterns of healthy eating while mitigating potential exposure to toxic elements through investments in early life nutrition offers one of FDA's greatest opportunities to have a profound impact on the nutrition, health, and well-being of a generation of Americans. Because toxic elements such as lead, arsenic, mercury, and cadmium, are present in the environment due to both their natural occurrence and introduction by human activities, a certain amount of exposure is unavoidable. The FY 2024 Budget continues support for FDA's Closer to Zero plan to expeditiously develop action levels and provide guidance on best practices for reducing and eliminating toxic elements in infant and toddler foods.

With additional resources, FDA will further improve its approach for regulating chemicals in the food supply. CFSAN will analyze whether its current program structure is appropriate to modernize this area and establish a modern data system to improve the Agency's ability to make science-based decisions on removing chemicals from food use or affirming their safe use. CFSAN will also hire additional FTE to expand the capacity of risk modelers, toxicologists, and chemists to prioritize risks and calculate optimal interventions.

Nutrition and Labeling: +$12.0 million / 19 FTE

Center: +$12.0 million / 19 FTE

The FY 2024 Budget provides $12.0 million for White House Nutrition Commitment and Food Labeling for CFSAN. The FY 2024 Budget will focus on the prioritization of nutrition and labeling work consistent with the White House Nutrition Conference.

One of the pillars of the White House's National Strategy on Hunger, Nutrition, and Health is to "empower all consumers to make and have access to healthy choices" through, among other things, providing consumers updated and more accessible food labeling and creating a healthier food supply and food environments so the healthier choice is the easier choice. The FY 2024 Budget will enable CFSAN to prioritize its nutrition and labeling work—a historically underfunded program—consistent with the Administration's pledge.

FDA has been charged with developing a front-of-package, standardized labeling system to communicate nutrition information to consumers more quickly. Such labeling schemes can promote equitable access to nutrition information and healthier choices; FDA will develop a standardized system to help consumers quickly and easily identify foods that are part of a healthy eating pattern. FDA will also make sure "healthy" labeling aligns with current nutrition science and the Dietary Guidelines for Americans with a proposal to update the nutrition standards for when "healthy" claims can be put on products, and will also develop a symbol to be used to depict and easily communicate a food as "healthy." FDA also plans to issue guidance on the use of Dietary Guidance Statements on food labels aimed at helping consumers understand how the

food can contribute to a healthy eating pattern. Additionally, FDA is requesting information on how best to facilitate making nutrition information easily available when shopping for groceries online.

After issuing voluntary, short-term sodium reduction targets in 2021, FDA will facilitate lowering sodium content of food further by proposing updated regulations to allow companies to use salt substitutes in standardized foods to give industry additional tools to produce foods lower in sodium; issue revised voluntary sodium reduction targets; and collaborate with federal partners to leverage the FDA sodium reduction targets in their nutrition assistance and other programs. Although the U.S. has reduced added sugar consumption and established a regulatory definition for "added sugars," intake is still too high for most Americans. FDA will assess the evidence base for further strategies to reduce added sugar consumption and collaborate with other federal partners to hold a public meeting regarding future steps to reduce intake of added sugars.

Emerging Chemical and Toxicological Issues: +$5.0 million / 8 FTE

Center: +$5.0 million / 8 FTE

The FY 2024 Budget provides an increase of $5.0 million to CFSAN for Emerging Chemical and Toxicological Issues. The FY 2024 Budget will support efforts to ensure safety of dietary supplements, reduce exposure to per-and polyfluoroalkyl substances (PFAS) and other chemicals that enter the food supply through contamination, and continue cross-agency efforts to reduce animal testing.

The new funding will advance CFSAN's efforts to assess the marketplace and reduce exposure to unsafe or otherwise illegal substances in dietary supplements. Even with modest funding increases in recent years, FDA's resources for dietary supplement regulation have not kept pace with growth in the market over time. Stakeholders, including consumer groups and trade associations are advocating for FDA to increase its enforcement and other regulatory activities. Additional resources for dietary supplement regulatory activities would help protect consumers by advancing the identification and evaluation of emerging ingredients in dietary supplements and conducting post-market safety review.

For chemicals that enter the food supply through contamination (e.g., environmental contamination such as PFAS, or process-induced contamination), FDA requires additional funding to reduce dietary exposures to the greatest extent feasible. This will include an assessment of the science related to the contaminants, such as the levels of exposure that have negative impacts on health. New funding will also support the science related to exposure—such as the foods that contribute to exposures—and the science related to mitigation—such as the steps growers and manufacturers can take to reduce the presence of the contaminant in food. The scientific assessment will inform risk management policies, such as the establishment of action levels, for reducing dietary exposures among the U.S. population.

The FY 2024 Budget will build on FY 2023 Omnibus investments to implement a cross-agency New Alternative Methods Program to initiate the adoption of new alternative methods for regulatory use that can replace, reduce, and refine animal testing (the 3Rs), as well as to improve predictivity of nonclinical testing to streamline the development of FDA regulated products and bring them to the U.S. public more rapidly and more efficiently while assuring they are safe, effective, and that patients and consumers can depend on them.

Food Supply Chain Continuity: +$2.0 million / 2 FTE

Center: +$2.0 million / 2 FTE

The FY 2024 Budget includes $2.0 million for CFSAN in staff and data investments that will strengthen the agency's ability to assess the health of supply chains and inform efforts to respond to shortages of critical foods. Recent events, such as the COVID-19 pandemic and current infant formula shortage, have illustrated the challenges posed by significant food supply chain disruptions, imbalances, and shortages. Ensuring the security and continuity of the food supply chain is also important to broader food security and equity issues. FDA regulates 80% of the U.S. food system and is therefore uniquely positioned to contribute data about food firms and facilities that can assist response efforts across government and the world.

The Budget will provide support for the agency's 21 Forward food supply chain continuity system, which has helped track supply chain shortages during the COVID-19 pandemic and inform ongoing work to track and anticipate supply disruptions across the infant formula supply chain.

Resources will allow FDA to integrate additional internal and external data sources into the 21 Forward food supply chain continuity system. These additional data sources include commercial data on the marketplace and foods sales down to the UPC and food label, providing insight into product availability and composition that may be leveraged for multiple purposes across the FDA Foods Program.

Modernization of Cosmetics Implementation: +2.5 million / 6 FTE

Center: +$2.5 million / 6 FTE

The FY 2024 Budget provides $5 million for the implementation of the Modernization of Cosmetics Regulation Act (MoCRA), including $2.5 million for the Office of Cosmetics and Colors. These resources will be used to hire additional staff to develop regulations, compliance policies, and submission platforms for registration and product listing; adverse event reporting; talc-containing cosmetics; labeling; and current Good Manufacturing Practices. MoCRA provides the most significant expansion of FDA authority to regulate cosmetics since 1938, but 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 is at risk.

The new funding will also support hiring additional experts to manage critical projects such as assessments of the use of PFAS in cosmetic products. This request will position FDA to begin efforts to facilitate industry compliance with and provide effective regulatory oversight of cosmetic products within scope of the MoCRA requirements.

Crosscutting: +$44.1 million / 9 FTE

Public Health Employee Pay Costs: +$39.9 million

Center: +$12.9 million

Field: +$27.0 million

The FY 2024 Budget provides $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and

Military FTE funded through budget authority. Within the Foods program $39.9 million is provided or pay costs, including $12.9 for CFSAN and $27.0 million for ORA.

OC Regulatory and Mission Support: +$2.1 million / 6 FTE

Center: +$680,000 / 1 FTE

Field: +$1.5 million / 5 FTE

The FY 2024 Budget provides $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within the Foods program, $2.1 million is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$2.1 million / 3 FTE

Center: +$672,000 / 1 FTE

Field: +$1.4 million / 2 FTE

The FY 2024 Budget provides an increase of $10.0 million, for a total of $28.0 million, including $2.1 million for the Foods program, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

The Foods Program began through the passage of the 1906 Pure Food and Drugs Act. The Foods Program's purpose is to protect and promote human health by ensuring the safety of the American food supply, dietary supplements, and cosmetics, as well as ensuring the proper labeling of food and cosmetics.

In collaboration with FDA's Office of Regulatory Affairs (ORA), the Center for Food Safety and Applied Nutrition (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 Efficient 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,[6] 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.[7]

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 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.[8]

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; and
- 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.

In May 2022, FDA announced increased flexibilities regarding the importation of certain infant formula products to bolster the availability of infant formula across the country while protecting

[6] 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.

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

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

the health of infants.[9] As of July 2022, these increased flexibilities have resulted in infant formula products from nine countries, with a total estimated quantity of 35 million pounds or more than 520 million full-size, 8-ounce bottles, headed to the U.S.

In July 2022, FDA announced the availability of educational resources for parents and caregivers about using the hundreds of millions of bottles worth of imported infant formula headed to the U.S. To help parents and caregivers recognize these imported products as they hit store shelves, FDA is creating "Names to Know" graphics featuring the label pictures and details about imported formulas. FDA has also posted a webpage that will be updated as additional products are exported to the U.S.[10]

In September 2022, FDA announced new guidance that will help provide a pathway for infant formulas operating under enforcement discretion in the U.S. to remain on the market.[11] This will help ensure the U.S. continues diversifying its infant formula market and make families less susceptible to shocks in the infant formula market.

In November 2022, FDA released an outline of a prevention strategy under development to prevent *Cronobacter sakazakii* illnesses associated with consumption of powdered infant formula.[12] FDA continues to work with manufacturers to maximize production and fill store shelves.

Advancing Health Equity through Improved Nutrition

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

Many nutrition-related chronic diseases are experienced disproportionally by racial and ethnic minority populations. For example, more than 4 in 10 American adults have high blood pressure, and that number increases to almost 6 in 10 for African American adults. FDA's Foods Program, in partnership with the Agency's Office of Minority Health and Health Equity, has a unique role to play to support federal initiatives that encourage industry to reformulate healthier food options for all, including foods provided through public assistance programs to children, as well as empowering consumers to make decisions that support a healthy diet through more accessible labeling and nutrition education including programs targeted to specific at-risk populations.

In October 2021, FDA issued a final guidance, "Voluntary Sodium Reduction Goals: Target Mean and Upper Bound Concentrations for Sodium in Commercially Processed, Packaged, and Prepared Foods," which provides voluntary short-term sodium reduction targets for food manufacturers, chain restaurants and food service operators for 163 categories of processed, packaged, and prepared foods. The guidance is another step the Agency is taking to advance the

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

[10] https://www.fda.gov/food/infant-formula-guidance-documents-regulatory-information/enforcement-discretion-manufacturers-increase-infant-formula-supplies

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

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

Administration's whole-of-government approach to nutrition and health and improve future health outcomes.[13]

In September 2022, FDA issued a proposed rule to update the definition of the nutrient content claim "healthy." The "healthy" claim can act as a quick signal on food package labels to help empower consumers, including those less knowledgeable about nutrition, with information to identify foods that will help them build healthy eating patterns. This action is just one part of the Agency's ongoing commitment to reduce diet-related chronic diseases and advance health equity. In addition to the proposed rule, FDA joined the "September White House Conference on Hunger, Nutrition, and Health," highlighting the Agency's support of the national strategy to improve nutrition and health and empower all consumers to be able to make, and to have access to, healthy food choices.[14]

FDA is also researching implementing a symbol that manufacturers could use on the front of packaging to show that their product meets FDA's definition of the "healthy" claim. Having a standardized graphic to show that a food qualifies for the "healthy" claim would further support the agency's goal of helping consumers more easily identify packaged food products that help them build healthy eating patterns.

The FDA Food Safety Modernization Act

FDA is transforming the nation's food safety system from reactive to proactive 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. FSMA also gives FDA new enforcement authorities to achieve higher rates of industry compliance with prevention and risk-based food and feed safety standards, as well as for FDA and industry to better and more quickly respond to and contain food safety problems when they do occur.

In December 2021, FDA issued a final rule establishing the Laboratory Accreditation for Analyses of Foods (LAAF) program as required by FSMA.[15] Under the LAAF program, FDA will recognize accreditation bodies that will accredit food testing laboratories to standards established in the final rule. In July 2022, FDA announced its recognition of six accreditation bodies under the LAAF program.

The establishment of the LAAF program is improving FDA's capacity to protect U.S. consumers from unsafe food by improving the accuracy and reliability of certain food testing through the uniformity of standards and enhanced oversight of participating laboratories.

In November 2022, FDA issued a final rule on food traceability designed to facilitate faster identification and rapid removal of potentially contaminated food from the market, resulting in fewer foodborne illnesses and deaths.

At the core of the 2022 final rule is a requirement 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. Under the new rule, covered firms, farms, retail food

[13] https://www.fda.gov/news-events/press-announcements/improve-nutrition-and-reduce-burden-disease-fda-issues-food-industry-guidance-voluntarily-reducing

[14] https://www.fda.gov/food/cfsan-constituent-updates/fda-proposes-update-definition-healthy-claim-food-labels

[15] https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-laboratory-accreditation-analyses-foods-laa

establishments, and restaurants will be required to provide information to FDA within 24 hours, or otherwise to some reasonable time to which FDA agrees, if requested for by the covered entity.

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.[16]

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 stronger food safety cultures.

In October 2022, FDA co-hosted a webinar with Stop Foodborne Illness,[17] a non-profit public health organization, as a part of their collaborative series that explores food safety culture.[18] The webinar series, entitled "Collaborating on Culture in the New Era of Smarter Food Safety," engages experts from the public and private sectors in a collaborative exchange of ideas and experiences related to the importance of building a robust food safety culture.

Improved Outbreak Response

The Coordinated Outbreak Response and Evaluation (CORE) Network coordinates the Agency's efforts to find, reduce, and work to prevent outbreaks of illness related to food, cosmetics, and dietary supplements. This team coordinates activities across FDA's field and compliance offices, state investigative and laboratory resources, and local city and county resources. CORE works with other federal agencies, such as the Centers for Disease Control and Prevention (CDC) and U.S. Department of Agriculture (USDA), to ensure timely and effective resolution of foodborne illness outbreaks.

In December 2021, FDA released the Foodborne Outbreak Response Improvement Plan to enhance the speed, effectiveness, coordination, and communication of investigations into outbreaks of foodborne illness. Working in concert with the New Era of Smarter Food Safety Blueprint, the plan is designed to improve FDA's ability to identify the sources and causes of foodborne illness outbreaks. These improvements will help to reduce the number of foodborne outbreaks that go unsolved and ultimately bend the curve of foodborne illness in this country.

In April 2022, FDA hosted a webinar for stakeholders to explain and answer questions about the Foodborne Outbreak Response Improvement Plan with the goals of raising awareness, enhancing understanding, and building support for the Plan. More than 1,600 registrants from 45 countries joined the webinar.[19]

Improved Pathogen Detection and Traceability

The Agency initiated the GenomeTrakr Network (the Network) in 2012, which has grown to include federal, state, hospital, and other labs in the U.S., as well as in other nations that use

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

[17] https://stopfoodborneillness.org/

[18] https://www.fda.gov/food/workshops-meetings-webinars-food-and-dietary-supplements/collaborating-culture-new-era-smarter-food-safety-10262022

[19] https://www.youtube.com/watch?v=bA-cqSo6UiI

whole genome sequencing (WGS) for pathogen identification. FDA continues to facilitate opportunities to speed the adoption of WGS by public and private laboratories. WGS and the Network also have roles in attaining the goals of the New Era of Smarter Food Safety Blueprint, which include facilitating opportunities to speed the sequencing of pathogens. Within foodborne genomic surveillance, the Foods Program and GenomeTrakr Network are advancing the One Health paradigm.[20]

The Network is now in its nineth year and has collected more than 710,000 whole bacterial genome sequences (including more than 390,000 Salmonella) from the FDA Network and collaborating sites. 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 certain outbreaks down to the farm level.

Applying WGS 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 WGS by public health labs via cloud computing analysis platforms, such as GalaxyTrakr;[21]
- 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 compliance with FDA's rules on safe food-handling practices.

The Foods Program applies WGS regularly to trace foodborne outbreaks for Shiga toxin-producing *E. coli* (STEC), *Salmonella*, and *Listeria monocytogenes*. By generating about two whole genomes per hour, GenomeTrakr is rapidly increasing the number of STEC, *Salmonella*, and *Listeria monocytogenes* genomes in the database. The network includes more than 70 state, international, FDA, and federal partner laboratories, further enhancing surveillance and genomic epidemiological linkage between clinical and environmental foodborne pathogens.

In 2022, FDA collected samples as a regular part of foodborne outbreak investigations and compliance actions; 132 separate WGS analyses were performed to support those activities. To date, more than 1,000 such analyses have been performed.

- **Domestic**: WGS data collected by FDA determined that the *Listeria* strain found in the facility of a Brie and Camembert cheese manufacturer matched the *Listeria* strain causing illnesses in this outbreak, which led to the manufacturer's voluntary recall. This investigation is ongoing.[22]

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

[21] https://galaxytrakr.org/

[22] https://www.fda.gov/food/outbreaks-foodborne-illness/outbreak-investigation-listeria-monocytogenes-brie-and-camembert-soft-cheese-products-september-2022

- **International**: In 2022, WGS has been integral in helping international agencies work together by unambiguously tying together product and clinical cases of Listeriosis associated with enoki mushrooms.
- **Recall and Import Scoping**: WGS has been instrumental to understanding 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 infant formula facilities, powdered infant formula product, and ill infants would have helped better inform public health officials and the public.[23]
- **Good Agricultural Practices**: WGS has played a key role in understanding risks in agricultural practices and how to moderate those risks (e.g., recently in Indiana to aid in understanding the scope of regional contamination).

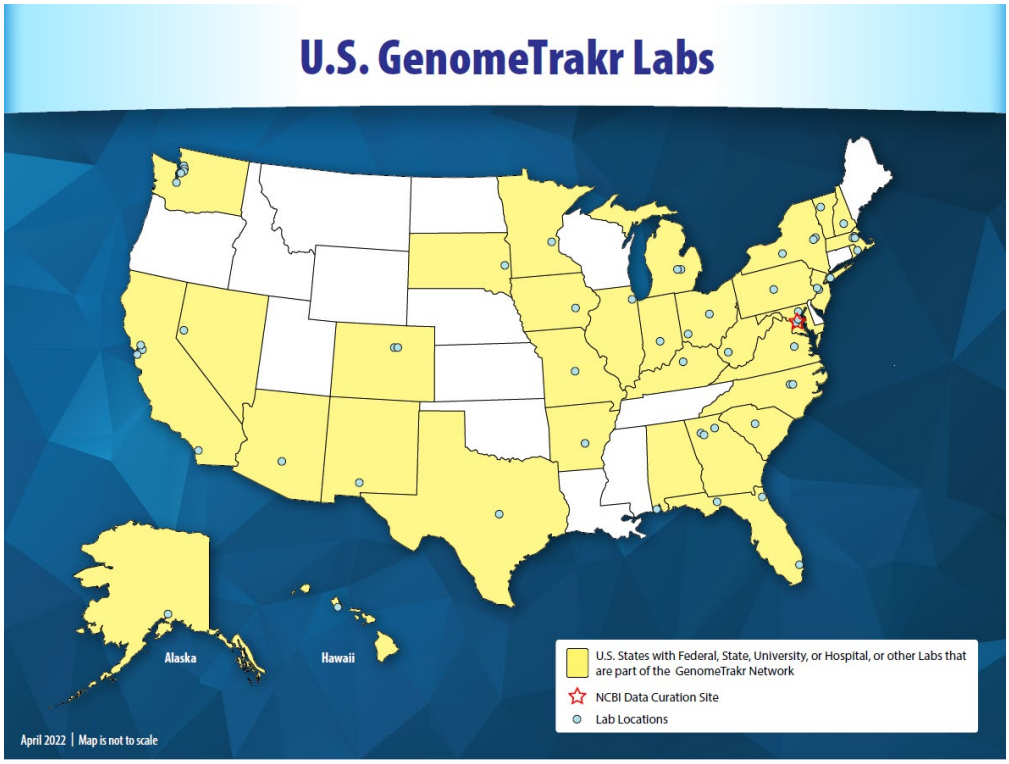


Figure 23 - U.S. Map of GenomeTrakr

Interagency Food Safety Analytics Collaboration 2022-2023

The Interagency Food Safety Analytics Collaboration (IFSAC) has published its priorities for calendar years 2022–2023[24] and is also extending the goals and objectives outlined in IFSAC's most recent strategic plan (2017–2021),[25] with special emphasis on incorporating data from sporadic (non-outbreak associated) illnesses to estimate sources of foodborne illness.

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

[24] https://www.cdc.gov/foodsafety/ifsac/pdf/IFSAC-2022-2023-Interim-Strategic-Plan-508.pdf

[25] https://www.cdc.gov/foodsafety/pdfs/IFSAC-Strategic-Plan-2017-2021.pdf

In November 2022, the Interagency Food Safety Analytics Collaboration's (IFSAC) published its newest annual report, "Foodborne illness source attribution estimates for 2020 for *Salmonella, Escherichia coli O157*, and *Listeria monocytogenes* using multi-year outbreak surveillance data, United States."[26]

Unlike prior IFSAC Annual Reports,[27] attribution estimates for *Campylobacter* are not presented in this year's report. Evidence suggests the sources of *Campylobacter* outbreaks likely differ considerably from the sources of non-outbreak-associated illnesses caused by this pathogen. IFSAC is exploring alternative approaches for estimating the sources of *Campylobacter* illnesses.

Regularly updated estimates, combined with other data, help shape FDA's priorities and inform the creation of targeted interventions to reduce foodborne illnesses caused by these pathogens. These estimates also inform stakeholders and improve our ability to assess whether prevention measures are working.

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; and
- 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, either by petition for a food additive or a color additive, or through notification programs for food contact substances and GRAS food ingredients. In FY 2022, FDA ensured safe access to the food supply by reviewing five Food Additive or Color Additive Petitions, 62 GRAS notifications, and 83 premarket notifications for Food Contact Substances.

FDA Issues Update on Recent Activities Pertaining to PFAS in Food

In July 2022, FDA made available testing results for per- and polyfluoroalkyl substances (PFAS) in seafood samples collected at retail.[28] FDA conducted this limited survey as a preliminary step to determine if a more targeted or larger seafood survey should be conducted. FDA tested 81 samples of clams, cod, crab, pollock, salmon, shrimp, tuna, and tilapia, most of which were imported to the United States. FDA evaluated individually the PFAS detected that have toxicological reference values. The Agency determined, for example, that the estimated exposure to perfluorooctanoic acid (PFOA), a type of PFAS, from the samples of canned clams,

[26] https://www.cdc.gov/foodsafety/ifsac/pdf/P19-2020-report-TriAgency-508.pdf

[27] https://www.cdc.gov/foodsafety/ifsac/annual-reports.html

[28] https://www.fda.gov/food/cfsan-constituent-updates/fda-shares-results-pfas-testing-seafood

which were from China, is likely a health concern. For the canned clam samples with the two highest levels of PFOA, there would be a potential health concern for consumers who eat more than approximately 10 ounces (oz) of these clams per month, except for young children, who should limit consumption to 2 oz per month.

Research has shown that exposure to PFOA is associated with several serious health outcomes, including developmental effects, changes to liver function, reduced immune response, and increases in certain types of cancer. The levels of the other types of PFAS evaluated in the clams, as well as the PFAS evaluated for all other seafood samples were found to likely not be a health concern. FDA is working to determine the extent of PFOA in imported canned clams and PFAS in clams overall and is taking action to ensure the continued safety of the U.S. food supply.

After learning the results of FDA's testing in their products, the two distributors of the samples with the two highest levels of PFOA took voluntary recall action.

FDA is actively engaged with all canned clam distributors that had products sampled to better understand potential sources of contamination, which could help the firms take action to reduce consumer exposure to PFOA from their products. In addition, the agency plans to conduct broader testing of canned and fresh clams to better understand PFAS levels so it can determine the best approach for protecting public health

FDA Works to Increase the Safety of 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"[29] identifies actions the Agency will take to reduce exposure to toxic elements from foods eaten by babies and young children to as low as possible.

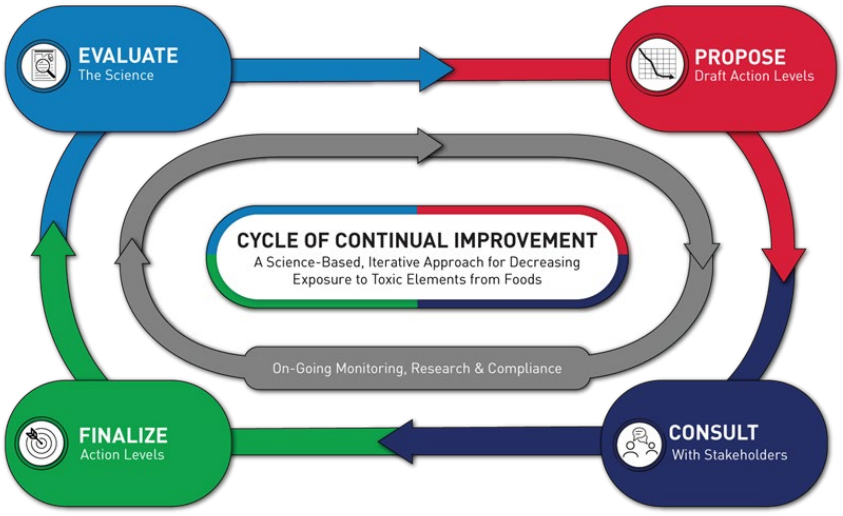


Figure 24 - Closer to Zero Action Plan's Cycle of Continual Improvement

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

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

In April 2022, FDA issued draft guidance to industry providing action levels for lead in single-strength (ready to drink) apple juice and in other single-strength juices and juice blends. The draft guidance, titled "Action Levels for Lead in Juice; Draft Guidance for Industry," provides an action level for lead in apple juice of 10 parts per billions (ppb), which is lower than the action level for lead in other juices (20 ppb), because, as the most commonly consumed juice by young children, apple juice may contribute a greater share of their potential lead exposure than other juices.[30] The FDA has prioritized reducing lead exposure because it is associated with serious health effects, including effects on the developing brain, such as impaired intellectual development.

These draft action levels support the Agency's broader effort to reduce exposure to arsenic, lead, cadmium, and mercury from foods and advance its goals in the Closer to Zero Action Plan.

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.

Inform Consumers and Patients

The Foods Program is responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled so that consumers and patients are equipped to make well-informed food choices. The Nutrition Labeling and Education Act (NLEA) requires most packaged foods to bear nutrition labeling and requires food labels that bear nutrient content claims and certain health messages to comply with specific requirements.

Encouraged the Safe Production of Dietary Supplements

In FY 2021, FDA's operations and oversight, including inspection activities, continued to be impacted by the COVID-19 pandemic. While fewer dietary supplement facility inspections were conducted in FY 2021 as compared with previous years, the Agency's overall dietary supplement compliance activity continued and resulted in:

- 111 warning letters;
- 1,299 import refusals;
- 3 injunctions (filed);
- 1 seizure; and
- 22 criminal convictions.

FDA continued to emphasize regulatory actions aimed at protecting consumers from dangerous or otherwise unlawful products–including fraudulent products that were, in some cases, marketed as dietary supplements. These included products making unlawful claims related to COVID-19, as well as claims to cure, treat, mitigate, or prevent diabetes, depression and other mental health disorders, and infertility. In addition, FDA also posted 69 public notifications for products that have been found to be tainted with undeclared drugs, many of which are marketed as dietary supplements.

Premarket notification of new dietary ingredients (NDIs) is FDA's only opportunity to identify potentially unsafe supplements before they are available to consumers. In FY 2021, FDA

[30] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/draft-guidance-industry-action-levels-lead-juice

responded to 49 NDI notifications. FDA acknowledged 27 of the notifications submitted with no objection. Of the remaining 22 notifications, FDA raised safety or identity concerns with 11, seven were determined to not pertain to a dietary ingredient or dietary supplement, and four were deemed incomplete.

In FY 2021, FDA received more than 2,400 adverse event reports (AERs) related to dietary supplements. The reports are evaluated by clinical reviewers in CFSAN to monitor the safety of consumer products.

Launched New Dietary Supplement Education Initiative

FDA has launched a new education initiative titled "Supplement Your Knowledge," to broaden public understanding of dietary supplements.[31] The initiative is designed to: help consumers learn more about dietary supplements; help educators and high school students learn to evaluate the accuracy and credibility of information they see and hear about dietary supplements; and help physicians and other healthcare professionals expand their knowledge about dietary supplements.

Supplement Your Knowledge resources will provide reliable information about the potential benefits and risks associated with dietary supplements, such as vitamins, minerals, and herbs they may consume.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
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 2021: 100% Target: 80% (Target Exceeded)	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 2022: 912 enrolled Target: 895 enrolled (Target Exceeded)	927	942	+15
212415: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Shiga toxin-producing Escherichia	CY 2021: 4.6 cases/100,000 (Target Not Met)	4.3	4.2	-0.1

[31] https://www.fda.gov/food/information-consumers-using-dietary-supplements/supplement-your-knowledge

Measure	Year and Most Recent Result/Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
coli (STEC) infections. (Outcome)				
212416: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Listeria monocytogenes infections. (Outcome)	CY 2021: 0.3 cases/100,000 (Target Not Met)	0.25	0.25	Maintain
212417: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Salmonella infections. (Outcome)	CY 2021: 13.1 cases/100,000 (Target Met)	14.0	13.7	-0.3
214307: Accuracy rate for confirmation of presumptive STEC positives from leafy green samples. (Output)	FY 2022: 30% colony confirmation for presumptive positives (New measure, Historical Baseline)	40% colony confirmation for presumptive positives	50% colony confirmation for presumptive positives	+10%
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2022: 97.7% 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 2022: 72.7%Target: 65% (Target Exceeded)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2022: 13 labs Target: 13 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 2022: 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

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 requires 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 exceeded the FY 2020 target of 80% by reviewing and completing 89% of the petitions received within 360 days of receipt.

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 2022 actual enrollment number of SLTT in the Retail Program Standards reflects an annual increase of 32 enrollments from the year-end FY 2021 total enrollments (880). 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 2023 and FY 2024 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% 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.[32] Widespread public health interventions implemented to prevent SARS-CoV-2 transmission might have contributed to this decrease in detection of illnesses. In CY 2021, the incidence of domestically-acquired infections caused by Salmonella decreased and incidence of domestically-acquired infections caused by STEC and *Listeria monocytogenes* increased slightly.[33]As in 2020, behavioral modifications and public health interventions implemented to control the COVID-19 pandemic might have decreased transmission of enteric infections. Continued surveillance might improve the

[32] 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

[33] Collins JP, 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, 2016–2021. MMWR Morb Mortal Wkly Rep 2022;71:1260–1264. DOI: http://dx.doi.org/10.15585/mmwr.mm7140a2

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. Because of these uncertainties, CFSAN is keeping the original FY 2023 and 2024 targets consistent with Healthy People 2030 in place for now, 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 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, with an increase target of +10 percent confirmation for presumptive positives for each FY 2023 and 2024. 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.

PROGRAM ACTIVITY DATA

Foods Program Activity Data			
CFSAN Workload and Outputs	**FY 2022 Estimate[8]**	**FY 2023 Estimate[8]**	**FY 2024 Estimate**
Food and Color Additive Petitions			
Petitions Filed [1]	10	10	10
Petitions Reviewed [2]	10	10	10
Premarket Notifications for Food Contact Substances			
Notifications Received	94	94	94
Notifications Reviewed [3]	94	94	94
Infant Formula Notifications			
Notifications Reviews Due to Be Completed [4]	45	45	45
Notification Reviews Completed Within 90 Days of Filing [5]	45	45	45
FDA Review Time	150 days	150 days	150 days
New Dietary Ingredient Notifications			
Notification Reviews Due to Be Completed	52	52	52
Notification Reviews Completed Within 75 Days of Filing [6]	52	52	52
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] 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.

[7]Since mid-March 2020, FDA operations and FDA oversight of the U.S. food supply have been significantly impacted by the COVID-19 pandemic. The Agency's priorities during this time period have been the safety of our staff, conducting mission-critical activities, including inspections, responding to foodborne disease outbreaks, sampling and testing of imported food, and managing recalls. We have also worked to support continuity of the food supply chain, which includes keeping food and agricultural workers safe to allow continued production of food. Given these priorities, and state and local travel restrictions, FDA adjusted its approach to oversight activities.

[8]As of January 19, 2021, the Infant Formula Program began informing those firms providing new infant formula submissions that FDA would need up to an additional 60 days to complete its reviews of those submissions. As of November 19, 2021, this review extension time period changed to 180 days.

Figure 25 - CFSAN Workload and Outputs

Field Foods Program Activity Data (PAD)			
Field Foods Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,099***	***7,661***	***7,661***
Domestic Food Safety Program Inspections	4,523	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	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	90		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	208		
Domestic Fish & Fishery Products (HACCP) Inspections	573		
Import (Seafood Program Including HACCP) Inspections	120		
Juice HACCP Inspection Program (HACCP)	111		
Interstate Travel Sanitation (ITS) Inspections	492		
Domestic Field Exams/Tests	*1,200*	2,082	2,082
Domestic Laboratory Samples Analyzed	*13,603*	15,164	15,164
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***304***	***1,230***	***1,230***
All Foreign Inspections	*304*	1,230	1,230
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***7,403***	***8,890***	***8,890***
IMPORTS			
Import Field Exams/Tests[2]	*94,353*	140,673	140,673
Import Laboratory Samples Analyzed	*14,163*	17,609	17,609
Import Physical Exam Subtotal	**108,516**	**158,282**	**158,282**
Import Line Decisions	19,344,104	19,537,545	19,732,920
Percent of Import Lines Physically Examined	0.56%	0.81%	0.80%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***5,761***	***7,106***	***7,106***
State Contract Food Safety (Non HACCP) Inspections	4,952	6,263	6,263
State Contract Domestic Seafood HACCP Inspections	492	679	679
State Contract Juice HACCP	$31	$46	$46
State Contract LACF/Acidified Food Inspections	84	101	101
State Contract Foods Funding	$12,780,932	$12,908,741	$13,037,828
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***13,164***	***15,997***	***15,997***

[1] The FY 2021 actual unique count of foreign inspections includes 77 OGPS inspections (57 for China, 2 for India, & 18 for Latin America).

[2] ORA is currently evaluating the calculations for future estimates.

[3] State partnership inspections have been removed from the PAD as they have been phased out. All state inspections are now accounted for under the "state contract" inspection category.

[4] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 26 - Field Foods Program Workload and Outputs

Field Cosmetics Program Activity Data (PAD)			
Field Cosmetics Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***52***	***65***	***65***
Domestic Inspections	52	65	65
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***3***	***0***	***0***
Foreign Inspections	3	0	0
IMPORTS			
Import Field Exams/Tests[1]	3,869	4,883	4,883
Import Laboratory Samples Analyzed	286	290	290
Import Physical Exam Subtotal	**4,155**	**5,173**	**5,173**
Import Line Decisions	3,868,699	3,907,386	3,946,460
Import Line Decisions	0.11%	0.13%	0.13%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***55***	***65***	***65***

[1]ORA is currently evaluating the calculations for future estimates.

[2]In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 27 - Field Cosmetics Program Workload and Outputs

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); and Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (PL 117-180).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Human Drugs	**1,995,820**	**2,006,214**	**2,116,644**	**2,282,747**	**2,381,802**	**99,055**
Budget Authority	***682,861***	***688,844***	***714,446***	***760,494***	***775,446***	***14,952***
User Fees	***1,312,959***	***1,317,370***	***1,402,198***	***1,522,253***	***1,606,356***	***84,103***
Center	1,756,077	1,768,212	1,851,926	1,998,525	2,087,880	89,355
Budget Authority	507,431	509,915	518,135	549,993	560,040	10,047
User Fees	1,248,646	1,258,297	1,333,791	1,448,532	1,527,840	79,308
Field	239,743	238,002	264,718	284,222	293,922	9,700
Budget Authority	175,430	178,929	196,311	210,501	215,406	4,905
User Fees	64,313	59,073	68,407	73,721	78,516	4,795
FTE	**6,478**	**6,725**	**6,782**	**6,825**	**6,847**	**22**

Figure 28 - Human Drugs Funding History Table

The FY 2024 President's Budget for the Human Drugs Program is $2,381,802,000 of which $775,446,000 is budget authority and $1,606,356,000 is user fees. The budget authority increases by $14,952,000 compared to the FY 2023 Enacted Budget. User Fees increase by $84,103,000. The Center for Drug Evaluation and Research (CDER) amount in the request is $2,087,880,000. The Office of Regulatory Affairs (ORA) amount is $293,922,000.

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 2024 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 2024 Budget will also enable FDA to continue efforts to support one of its highest priorities—the goal of ending the overdose crisis—and will carry forward the agency's support of the development of abuse-deterrent formulations as one of many strategies intended to mitigate the harms associated with prescription opioid analgesic abuse while maintaining legitimate access to opioid analgesics for patients who need them. FDA is responsible for the thoughtful regulation of the drugs used in the treatment of pain, as well as the treatment of substance use disorder and overdose, and aims to ensure that the actions it takes are in the best interest of public health and support the nation's response to the overdose crisis. As drug overdose deaths continue to increase in the U.S., further research is needed to address this crisis, including the impact of COVID-19 on patients with substance use disorder.

With the FY 2024 Budget, FDA will advance efforts to facilitate access to investigational therapies for neurodegenerative diseases such as amyotrophic lateral sclerosis (a.k.a. Lou Gehrig's disease), a progressive and fatal disease. FDA continues to recognize the critical unmet medical need for new, effective treatments for this poorly understood disease and will utilize this

funding to support research and the development of interventions intended to prevent, diagnose, mitigate, treat, or cure ALS and other rare neurodegenerative diseases.

The FY 2024 Budget also will build on efforts to strengthen FDA's drug safety surveillance and oversight of marketed drug products. Investments will be used to modernize FDA's regulatory framework and create and implement organizational and procedural changes to support efficient and effective postmarket safety for the 21st century. Continuous enhancements to FDA's drug surveillance and safety oversight program will help the Agency better leverage the advances in drug safety science to protect the health of the American public.

BUDGET AUTHORITY

FY 2024 President's Budget: Human Drugs *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Enacted	**549,993**	**210,501**	**760,494**
FY 2024 Budget Authority Changes	10,047	4,905	14,952
Advancing Medical Product Safety	**24,881**	**2,300**	**27,181**
Postmarket Safety Collaborative	4,100	-	4,100
Advancing the Goal of Ending the Opioid Crisis	19,550	2,300	21,850
ACT for ALS	1,231	-	1,231
Investing in Core Operations - Crosscutting	**22,145**	**7,888**	**30,033**
Enterprise Data and IT Modernization	3,156	406	3,562
Public Health Employee Pay Costs	15,722	7,054	22,776
OC Regulatory and Mission Support	3,267	428	3,695
Other Adjustments	**(36,979)**	**(5,283)**	**(42,262)**
ORA Transfer to HQ/OGPS	-	(3,630)	(3,630)
FDARA Sec. 905 BA Shift	(39,667)	(2,002)	(41,669)
Comparability Adjustment	2,688	349	3,037
FY 2024 Budget Net Total: Human Drugs	**560,040**	**215,406**	**775,446**

Figure 29 - Human Drugs Budget Authority

Medical Product Safety: +$27.2 million / 18 FTE

Postmarket Safety Collaborative: +$4.1 million / 5 FTE

Center: +$4.1 million / 5 FTE

The FY 2024 Budget provides $10.1 million for Strengthening FDA Postmarket Safety Collaborative, including $4.1 million for the Human Drugs program.

As part of its mission to protect public health and safety, FDA's postmarket surveillance program continuously monitors the safety of all drug products while they are being marketed. When information that may change the benefit-risk profile of a product is uncovered, FDA investigates the issue and takes appropriate action. These actions may include requesting or requiring labeling changes, issuing drug safety communications, requiring postmarket studies, requiring or modifying risk evaluation and mitigation strategies (REMS), or withdrawing approval of a product. The Agency maintains a wide-ranging postmarket surveillance and risk

evaluation program to identify and evaluate new adverse events and medication errors—those that did not appear during the drug development and approval process. Although clinical trials provide important information on a drug's efficacy and safety, it is impossible to have complete information about the safety of a drug at the time of its approval. The true picture of a medical product's safety can evolve over the months, and years of the product's lifetime in the marketplace. Protecting the health of the American public requires FDA to continuously enhance its drug safety surveillance and oversight program, consistent with advances in the science of drug safety.

FDA currently faces significant challenges to its ability to maintain an efficient and effective postmarket safety surveillance program. Staffing levels have not kept pace with the increasing amount of postmarket work from the growing number and complexities of recent approvals, and the increasing amount of data needing review. In order to leverage the rapid advances in the science of drug safety, FDA needs to update its scientific standards and modernize its assessment tools, approaches, organizational structure, and processes to enable FDA scientists to effectively and efficiently aggregate and analyze important drug safety data to protect the American public.

Advancing the Goal of Ending the Opioid Crisis: +$21.9 million / 10 FTE

Center: +$19.6 million / 5 FTE

Field: +$2.3 million / 5 FTE

The FY 2024 Budget includes an increase of $23.0 million for Advancing the Goal of Ending the Opioid Crisis, including $19.6 million for CDER and $2.3 million for ORA.

CDER requests $19.6 million to advance the goal of ending the overdose crisis and to support the substantial work that is needed to implement the SUPPORT Act, enacted in October 2018. The SUPPORT Act gave FDA new authorities to continue current opioid-related efforts and new directives to implement policy actions to help patients in need while also reducing the use, misuse, and abuse of opioid medicines. FDA will use the funding to further develop and advance strategies to confront the overdose crisis through the Agency's Overdose Prevention Framework:

- Supporting primary prevention by eliminating unnecessary initial prescription drug exposure and inappropriate prolonged prescribing
- Encourage harm reduction through innovation and education
- Advancing development of evidence-based treatments for substance use disorders
- Protecting the public from unapproved, diverted, or counterfeit drugs presenting overdose risks

The Framework is further guided by four cross-cutting principles: equity; data and evidence; coordination, collaboration, and integration; and stigma reduction.

Critical areas related to appropriate pain management as well as the use, misuse, and abuse of opioid analgesics demand science-based study and analysis. Research will include collecting, generating, and analyzing pre-clinical, clinical, and real-world data needed to validate clinical endpoints for drug development and help identify new drug targets. Studies will inform better pain management as well as the development of novel treatments for overdose reversal and substance use disorder. Findings from these studies will support the agency's ongoing opioid initiatives, which include industry guidance clarifying FDA's thinking on clinical trial designs

and help sponsors bring novel treatments to market for acute pain, chronic pain, opioid overdose reversal, and substance use disorder.

The requested funding will advance the development of evidence-based clinical practice guidelines for acute pain. Implementing Sec. 3002 of the SUPPORT Act, FDA will work collaboratively with relevant professional organizations to support the development and adoption of evidence-based clinical practice guidelines. Funding will also support FDA's implementation of Sec. 3032 of the SUPPORT Act, which provided FDA with new authority to mandate safety-enhancing packaging and disposal technologies for opioids and other drug products that carry serious risks of abuse or overdose.

The FY 2024 Budget will support FDA's use of modern approaches and IT solutions, including the expansion of using social media data to analyze real-world patterns of opioid use, misuse, and abuse. FDA will also continue working to transition and maintain the Opioid Data Warehouse to the CDEROne platform – a cloud-based enterprise data lake and augmented analytical platform – to support opioid data analysis, including an expansion to capture all transactional information not currently available in CDEROne. Together, these efforts are critical to foster the safe use of opioids and detect new potential emerging threats.

Funding will also provide staffing to support FDA's opioid policy programs. The overdose crisis is rapidly evolving and has been further complicated by the impact of the COVID-19 pandemic. As drug overdose deaths remain exceedingly high, additional staff are needed – now more than ever – to sustain FDA's critical work in this area.

ACT for ALS: +$1.2 million / 3 FTE

Center: +$1.2 million / 3 FTE

The FY 2024 Budget includes an increase of $2.5 million, including $1.2 million for CDER to implement ACT for ALS, including implementation of the ACT for ALS Action Plan, and operation of the Public Private Partnership (PPP).

The FY 2024 Budget will provide FDA with resources to implement activities outlined in the ACT for ALS action plan by hiring additional FTE. Within CDER, this includes supporting the PPP that NIH and FDA launched with Critical Path as the convener. Through cooperative agreements or contracts, this PPP will advance the understanding of rare neurodegenerative diseases and foster the development of treatments for amyotrophic lateral sclerosis and other rare neurodegenerative diseases. To be successful, this will not only require funding to support the PPP but equally as important, it will require FDA to be able to actively engage with stakeholders who are part of this PPP, including patient groups. FDA's regulatory and scientific expertise will be critical to assure that the initiatives supported are more likely to successfully translate into new therapeutics.

FDA has also published a five-year Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis, as required under the ACT that outlines a strategy and supportive organizational infrastructure to advance innovation that promotes and accelerates medical product development for the treatment of rare neurodegenerative diseases such as amyotrophic lateral sclerosis (ALS).[34] This plan includes an ALS Scientific Strategy. FDA's ability to carry

[34] https://www.fda.gov/media/159372/download

out the strategic objectives outlined in this action plan is dependent on further resources. Finally, both the PPP and FDA's activities under the action plan will identify scientific gaps for which targeted research will be needed to advance innovation. Specific funding for the rare neurodegenerative disease grant program is critical to support the other elements of the ACT for ALS.

Crosscutting: +$30.0 million / 11 FTE

Public Health Employee Pay Costs: +$22.8 million

Center: +$15.7 million

Field: +$7.1 million

The FY 2024 Budget includes $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTE funded through budget authority. Within the Human Drugs program, $22.8 million is provided for pay costs, including $15.7 million for CDER and $7.1 million for ORA.

OC Regulatory and Mission Support: +$3.7 million / 7 FTE

Center: +$3.3 million / 5 FTE

Field: +$428,000 / 2 FTE

The FY 2024 Budget includes $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within the Human Drugs program, $3.7 million is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$3.6 million / 4 FTE

Center: +$3.2 million / 3 FTE

Field: +$406,000 / 1 FTE

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $3.6 million for the Human Drugs program, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

USER FEES

Current Law User Fees: +$84.1 million

Center: +$79.3 million

Field: +$4.8 million

The Human Drugs Program request includes an increase of $84.1 million for user fees 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 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.

CDER's strong programmatic foundation continues to allow the center to advance its mission across its large portfolio of human drugs. The Center remains committed to continue building on that foundation to ensure patients have access to safe and effective drugs, and to support our public health partners, stakeholders, and industry to achieve this goal. CDER is implementing ongoing, strategic efforts for success in the short and long-term.

Leveraging our strong programmatic foundation has enabled CDER to advance therapies for myriad diseases while also launching an aggressive and multi-pronged approach to address the unexpected challenge of COVID-19. CDER's role is integral to the government's COVID-19 response effort. CDER is also helping to ensure that such treatments are evaluated in diverse populations, monitoring the supply of medicines and acting to prevent or mitigate drug shortages, and protecting the American public from fraudulent products that claim to diagnose, prevent, treat, or cure COVID-19.

Looking forward, CDER is identifying opportunities where these strategic efforts can build on our foundation and better support patients, industry, partners, and stakeholders and position the Center for success as we transition to a post-pandemic world.

Looking ahead to FY 2024, CDER is implementing strategic efforts to further strengthen our programmatic foundation, including focusing on innovation, promoting public health, assuring patient access, international regulatory convergence, drug safety, and health equity as discussed below. 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 patient's needs by supporting early and frequent communication with sponsors during drug development. Of the 36 novel drugs approved in FY 2022, 23 (64 percent) were approved first in the United States. Of these novel drugs, 23 (64 percent) were first-in-class, which may indicate the drug's potential for a strong positive impact on the health of the American people. Additionally, 26 of the FY 2022 novel drug approvals (including 17 of the first-in-class approvals) were designated in one or more of

the following expedited programs: fast track, breakthrough therapy, priority review, and accelerated approval, indicating the potential for the drug to fill an unmet medical need.[35]

To further facilitate drug development, in FY2022, the Office New Drugs published 23 guidances; 17 of which focused on specific areas for drug development including COVID-19, cancer, hepatitis B, and non-opioid analgesic for acute pain.

Drug Development Tools

Drug development tools (DDTs) can streamline drug development. FDA has taken a number of actions to advance DDTs, including, in 2022, launching a searchable web-based tool for sponsors to find out information about specific drug development tools. In 2022 the Agency has specifically focused on the following regulatory science efforts and selected accomplishments are highlighted.

Biomarker Qualification Program

As of the close for FY 2022 the Biomarker Qualification Program has over 80 biomarker projects under development. In FY 2022, FDA awarded a total of 8 research grants to support ongoing work in these programs and held two public workshops to discuss key issues regarding the use of biomarkers.

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 public health needs. Using a collaborative, multidisciplinary approach, program staff work directly with requestors to advise on development or modification of COAs. The program closed 2022 with 66 projects in various stages of qualification and currently has 2 LOIs under review but not yet accepted.

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

Accepted first submission to evaluate off-target protein binding for a variety of biotherapeutic modality, potentially reducing or eliminating the need to conduct more standard non-clinical toxicology tests.

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

Specific examples of how CDER uses in silico tools include:

- Generating critical evidence to support alternative drug dosing strategies, alleviating the need for additional clinical trials, aiding in assessing the effects of drug interactions or organ impairment on drug exposure in the absence of dedicated trials; and informing clinical management strategies.
- Collaborating with stakeholders to develop natural history models in neurological and rare diseases to evaluate new treatments in settings that are inherently hard to study and to develop a clinical trial simulation tool to optimize enrichment and design of efficacy studies in Parkinson's disease.

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

- Using in silico models to predict mutagenicity of drug impurities based on chemical structure, and to predict the arrhythmic risk thus alleviating the need for certain cardiac safety clinical trials.
- Predicting the binding characteristics of novel opioids, naloxone dosing requirements in the community setting for opioid overdose, and to inform labeling for reversal agents.
- Exploring new or existing compounds to treat COVID-19 and other serious unmet clinical needs, as well as identify drug combinations for treatment of viral diseases.

Patient Focused Drug Development
Specific examples of how CDER patient focused drug development include:

- Issuance of final guidance on methods to identify patient priorities regarding the burden of disease, as well as the benefits and risks of treatment.[36]
- Issuance of draft guidance on how to select, modify or develop fit-for purpose clinical outcome assessments.

Rare Disease Drug Development
In May 2022, CDER announced the launch of the new Accelerating Rare disease Cures (ARC) Program. The vision of CDER's ARC Program is speeding and increasing the development of effective and safe treatment options addressing the unmet needs of patients with rare diseases. Through scientific and regulatory innovation and engagement, CDER's ARC Program helps support the development and approval of safe and effective rare disease treatment options. In our first year, CDER's ARC Program is focused on strengthening internal and external partnerships with stakeholders and engaging with external experts to help identify solutions for challenges in rare disease drug development. CDER's ARC Program provides strategic overview and coordination of CDER's rare disease activities and works in close collaboration with other FDA rare disease partners such as the Center for Biologics Evaluation and Research and the Office of Orphan Products.[37]

FDA also released its Action Plan for Rare Neurodegenerative Diseases including Amyotrophic Lateral Sclerosis (ALS) – a five-year strategy that CDER will undertake to improve and extend the lives of people living with rare neurodegenerative diseases by advancing the development of safe and effective medical products and facilitating patient access to novel treatments. CDER, together with the CBER and CDRH, as well as NIH, launched a new public private partnership (PPP) with the Critical Path Institute as the convener. This new PPP, Critical Path for Rare Neurodegenerative Disease (CP-RND), will bring together multiple experts in rare neurodegenerative diseases, including ALS, as well as private entities, patient communities and advocacy organizations to accelerate and advance our understanding of disease pathology, treatment options, diagnostics, and drug development.

Health Equity
FDA is committed to encouraging diverse participation in research used to support marketing applications for regulated medical products and has made progress in this area over the years. Physicians' have greater confidence in extrapolating results from clinical investigations to their

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

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

own patients when the participants in a clinical investigation reflect the product's intended patient population as closely as possible.

The FDA is currently engaging in significant policy work relating to diversity in clinical investigations and in April 2022 issued a draft guidance on Diversity Plans to Improve Enrollment of Participants From Underrepresented Racial and Ethnic Populations in Clinical Trials.[38]

We view modernizing clinical investigation design and conduct and utilizing innovative technologies as areas to: enhance enrollment of diverse populations; facilitate the development of drugs, biological products, and improve efficiencies.[39] [40] [41]

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, and RWE has supported approvals of applications meeting evidentiary standards. For example, RWD/E was the basis for accelerated approval of alpelisib (Vijoice®) in April 2022 for adult and pediatric patients two years of age and older with severe manifestations of PIK3CA-related overgrowth spectrum (PROS) who require systemic therapy. FDA has also published a series of foundational draft guidances regarding the use of RWD, including assessing whether RWD, including registries, are fit for use.[42] [43] [44] [45] These foundational guidances will be followed by further guidance on trial and other study designs using RWD.

Advanced Manufacturing

Advanced manufacturing remains a high priority for CDER because it should help address significant challenges related to drug development, maintaining robust supply chains by limiting quality-related manufacturing interruptions, and emerging public health issues. Traditional manufacturing technologies and facilities do not provide sufficient flexibility and agility for adequate and timely responses to these urgent health issues.[46] [47]

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[38] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

[39] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial

[40] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/patient-engagement-design-and-conduct-medical-device-clinical-studies

[41] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations

[42] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-electronic-health-records-and-medical-claims-data-support-regulatory

[43] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/data-standards-drug-and-biological-product-submissions-containing-real-world-data

[44] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/real-world-data-assessing-registries-support-regulatory-decision-making-drug-and-biological-products

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

[46] https://www.fda.gov/science-research/focus-areas-regulatory-science-report/focus-area-advanced-manufacturing

[47] https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/advanced-manufacturing

In FY 2022, CDER's Emerging Technology Program (ETP) approved 5 applications under ETP, accepted 13 ETP proposals, and accepted 13 meetings with industry under ETP. In addition, the new 18,000 square foot advanced pharmaceutical manufacturing research facility is currently under construction in Ammendale, MD (Ammendale facility). This facility will improve CDER's capability to conduct mission-relevant testing, research and training for FDA staff in the area of emerging technologies. The Ammendale facility will address space constraints such as height limits for manufacturing equipment, enable the flow of material and staff, and provide flexibility in utilities to facilitate the development of pilot scale advanced manufacturing platforms. Construction on the laboratory suite is slated for completion in 2023.

FDA's work on advanced manufacturing has facilitated the approval of 15 applications to date that use advanced manufacturing (some including CM) for a variety of purposes including manufacturing of finished dosage forms, a dialysis solution, a top-selling active pharmaceutical ingredient, and a biological product; 3-D printing technology; advanced process analytical technologies for monitoring and control of a drug substance bioprocess; and a novel glass container closure system for a parenteral drug product.

International Harmonization and Regulatory Convergence

International efforts to develop converge on 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 Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)[48], FDA is continuing to advance harmonization projects. Currently over 30 ICH expert working groups comprised of FDA scientific and medical experts, and colleagues from other regulatory authorities and the pharmaceutical industry, are developing international guidelines to improve quality and efficiency of global drug development, manufacturing, and post-market safety oversight.[49]

Promoting Public Health

COVID Pandemic Response Activities

CDER's role is integral to the whole-of-government COVID-19 response effort. This past year, CDER expanded its proactive, multi-pronged approach to address the COVID-19 public health emergency by building on the Center's robust response structure established early in the pandemic. Working closely with our Federal colleagues within and outside of the Department of Health and Human Services, CDER's multidisciplinary teams helped ensure that the most promising treatments for COVID-19 were made available to patients as quickly as possible,[50] including two new EUAs in 2022 and three approvals for COVID therapeutics. In addition, CDER closely monitored the drug supply chain to prevent and mitigate shortages of critical medicines and protected the public from potentially dangerous products and false claims.[51] [52]

[48] https://www.ich.org/

[49] https://www.fda.gov/drugs/cder-international-program/international-regulatory-harmonization

[50] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/coronavirus-treatment-acceleration-program-ctap

[51] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/manufacturing-supply-chain-and-drug-inspections-covid-19

[52] https://www.fda.gov/drugs/coronavirus-covid-19-drugs/cders-work-protect-public-health-during-covid-19-public-health-emergency

Combating Antibiotic Resistant Bacteria

FDA continues to be actively involved in combatting antimicrobial resistance (AMR). FDA funded several research projects to facilitate the development of novel antibacterial products and optimizing the use of existing ones. FDA has also facilitated AMR-related research through interagency agreements, including research to evaluate animal models of bacterial infections, assessment of discordance between clinical and microbiological endpoints in complicated urinary tract infections and is conducting work to align regulatory requirements with other authorities in the design of bacterial pneumonia trials.[53]

Substance Abuse and Overdose Prevention

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.

FDA recognizes the risks of 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 opioids and other controlled substances and ameliorate the overdose crisis is among FDA's highest priorities. FDA is engaging in many activities aimed at furthering these goals.

In alignment with HHS' Overdose Prevention Strategy, FDA has identified four specific Overdose Prevention Priorities to provide a framework and focus for FDA's actions to address the crisis they include: [54]

- Supporting primary prevention;
- Encouraging harm reduction;
- Advancing evidence-based treatments; and
- Protecting the Public from Unapproved, Diverted, or Counterfeit Drugs Presenting Overdose Risks.

Highlights of FY2022 accomplishments include –the approval of ZIMHI (naloxone hydrochloride), a high dose (5 mg) injection as an additional option to treat opioid overdose and the approval of a second generic nasal naloxone product.

In addition, in April 2022- FDA and U.S. Drug Enforcement Administration issued joint warning letters to operators of two websites illegally selling Schedule II stimulants, including amphetamine drug products marketed as Adderall. FDA and U.S. Custom and Border Protection (CBP) agreed on a National Operational Strategy to further collaboration and information sharing and enforcement within international mail facilities (IMFs). The resulting operation,

[53] https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/antimicrobial-resistance-information-fda

[54] 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.

"Operation Opioid and Other Drugs," began in early FY 2022, specifically targeting unapproved drugs and illegal opioids at the IMFs and courier hubs.

Drug Safety and Compounding

Sentinel

The FDA Amendments Act of 2007 established FDA's Sentinel System, one of the world's premier real-world data (RWD) platforms. Sentinel remains one of the world's largest multi-site, privacy-preserving, medical product safety surveillance systems with highly curated data. Sentinel captures over 700 million person-years of longitudinal data and more than 65 million patients actively accruing new data. It also includes data on more than 5 million live-birth deliveries with a mother-infant linkage to support assessments of medication use in pregnancy. The Sentinel System has served as a fully integrated part of FDA's regulatory process for 7 years. In addition, FDA's Catalyst program leverages the Sentinel infrastructure and supplements it with data from interactions with health plan members and providers. [55] FDA continued to use the Sentinel system to monitor the safety of authorized COVID-19 therapeutics, as well as other CDER regulated products.

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 2022 FDA conducted over 75 inspections, issued 11 warning letters and 19 referral letters to state agencies, oversaw 30 recalls, obtained 1 injunction, and issued 2 compounding risk alerts[56] Also in FY 2022, FDA added the first four drugs to the list of bulk drug substances that may be used in compounding under section 503B, and issued a revised draft guidance on hospital and health system compounding under section 503A.[57]

Assuring 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 by providing for the collection of user fees to support FDA's biosimilar product review program activities. [58] In the past 5 years, FDA has approved 31 biosimilars, including 4 interchangeables, 2 for insulin. An interchangeable biosimilar can be substituted at the pharmacy much like generic drugs.

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. FDA estimates that in 2019 and 2020, generic drugs resulted in over $35 billion in savings for

[55] https://www.fda.gov/safety/fdas-sentinel-initiative#:~:text=Sentinel%20is%20the%20FDA's%20national,FDA%20launched%20the%20Sentinel%20Initiative.

[56] https://www.fda.gov/drugs/human-drug-compounding/compounding-risk-alerts

[57] https://www.fda.gov/drugs/human-drug-compounding/regulatory-policy-information

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

the American public.[59] FDA is working to further encourage robust and timely market competition for generic drugs and to help bring greater efficiency and transparency to the generic drug review process through our Drug Competition Action Plan and GDUFA III commitments.[60] [61] Complex drug products, e.g., drug-device combinations or complex formulations, is an area targeted by patients and industry as an unmet need for generic competition. FDA has published 39 new and 20 revised product-specific guidances describing FDA's current thinking on how to develop specific complex generic drugs and updated informational web pages, held public workshops and assisting 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 are no generic competition and in FY 2022 updated the List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic.

In addition, FDA continues to work to implement the law widely known as CREATES (Creating and Restoring Equal Access to Equivalent Samples Act), which provides a pathway for developers of generic, 505(b)(2), and biosimilar products to obtain access to samples needed for product development. FDA plans to issue guidance for industry on obtaining Covered Product Authorizations (CPAs) under CREATES. As of July 29, 2022, FDA has issued over 50 CPAs, all within the statutory timeframes. This ongoing work allows product developers to more easily obtain samples needed to support the submission of competing applications.

Drug Shortages

FDA's access-related work also includes addressing drug shortages. Shortages can worsen patients' health outcomes by causing delays in treatment or changes in treatment regimens, such as substituting second-line alternative therapies that may pose additional risks or be less effective than the preferred drug. Drug shortages can occur for many reasons, including manufacturing delays, quality problems, and discontinuations.[62] FDA continues to work closely with manufacturers to prevent shortages and to resolve those that occur, including by expediting manufacturing supplements and when appropriate extending expiry date or importing products that meet FDA's quality standards. FDA is also engaged with HHS in developing greater transparency into the supply chains.

Drug Supply Chain Security

FDA continues to establish the regulatory framework authorized under the Drug Supply Chain Security Act (DSCSA) that will enhance our ability to protect consumers from exposure to potentially harmful drugs through improved detection and removal of such products from the supply chain. Product Tracing, Identification and Verification: FDA will collaborate with prescription drug manufacturers, wholesale distributors, repackagers, and dispensers (primarily pharmacies) to implement enhanced drug distribution security requirements as required by statute.[63] [64]

[59] https://www.fda.gov/about-fda/center-drug-evaluation-and-research-cder/generic-competition-and-drug-prices

[60] https://www.fda.gov/drugs/guidance-compliance-regulatory-information/fda-drug-competition-action-plan

[61] https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs

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

[63] https://www.fda.gov/media/159302/download

[64] https://www.fda.gov/Drugs/DrugSafety/DrugIntegrityandSupplyChainSecurity/DrugSupplyChainSecurityAct/default.htm

IT Roadmap

A key to enable CDER to carry out its public health mission is being able to ingest and process a large volume of data received on our drug products. Being able to efficiently ingest and process such data is the key to our success. CDER is progressing its IT strategic roadmap, investing in workflow management, data and analytics, administrative efficiency, and technological modernization.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
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 2021: 85% Target: 90% (Target Not Met)	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 2021: 98% 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 2021: 93% 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 2021: 91% Target: 90% (Target Exceeded)	90%	90%	Maintain
223215: Review and act on 90 percent of standard original Abbreviated New Drug Application (ANDA) submissions within 10 months of receipt. (Output)	FY 2021: 96% 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 2021: 95% Target: 90% (Target Exceeded)	90%	90%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2022: 93.4% 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 2022: 56.8% Target: 55% (Target Exceeded)	55%	55%	Maintain
292203: Number of medical product analyses conducted through FDA's Sentinel Initiative. (Output)	FY 2022: 76 Target: 65 (Target Exceeded)	65	65	Maintain

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. Although the agency met three out of the four PDUFA performance goals, the agency fell short on the measure to review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60-day filing date. Four FY 2021 standard NME/BLA applications missed the user fee goal date due to COVID travel restrictions impacting the ability to inspect facilities. The agency will continually work to meet or exceed the review performance goals when possible, moving forward.

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. To date, the Sentinel Initiative has provided 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 numerous regulatory decisions. The Sentinel Initiative is comprised of multiple components including the Sentinel System, and its Active Risk Identification and Analysis (ARIA) program, FDA Catalyst, and the Biologics Effectiveness and Safety System. In 2022, FDA continued to leverage Sentinel as part of a multi-layered response to the COVID-19 pandemic. Some of these activities include near real-time drug monitoring to inform the potential for drug shortages, estimating the prevalence of medicines used among pregnant women with COVID-19, and assessing coagulopathy and its risk factors among hospitalized COVID-19 patients. 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 once they are 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.

PROGRAM ACTIVITY DATA

Human Drugs Program Activity Data (PAD)			
CDER Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
New Drug Review			
Workload – Submissions/Filings/Requests			
New Drug Applications/Biologic Licensing Applications (NDA/BLA)	111	158	147
Efficacy Supplements	229	227	223
Manufacturing Supplements	1,976	2,272	2,264
Commercial INDs (Drugs and Biologics) with Activity	9,549	10,389	11,136
Sponsor Requests: IND-Phase Formal Meetings	3,340	3,340	3,340
Sponsor Requests: Review of Special Study Protocols	149	149	149
Submissions of Promotional Materials	145,000	150,000	155,000
Outputs – Reviews/Approvals			
Reviews: Priority NDA/BLA	69	69	69
Reviews: Standard NDA/BLA	151	151	151
Approvals: Priority NDA/BLA	44	44	44
Approvals: Standard NDA/BLA	80	80	80
Mean time from Receipt to Approval: Priority NDA/BLAs (in months)	9	9	9
Mean time from Receipt to Approval: Standard NDA/BLAs (in months)	21	21	21
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)	12	12	12
Reviews: NDA Supplemental	2,806	2,806	2,806
Reviews: Clinical Pharmacology/ Bio-Pharmaceutic	9,360	9,996	10,769
Biologic Therapeutics Review			
Workload – Submissions/Filings/Requests			
Receipts: Commercial IND/IDE (Biologics Only)	363	363	363
Receipts: IND/IDE Amendments (Biologics Only)	31,666	31,666	31,666
Outputs – Reviews/Approvals			
Reviews: Total Original License Application (PLA/ELA/BLA)	28	28	28
Approvals: PLA/BLA	13	13	13
Reviews: License Supplement (PLA/ELA/BLA)	593	593	593
Generic Drug Review			
Workload – Submissions/Filings/Requests			
Receipts: Abbreviated New Drug Applications (ANDA)	850	850	850
Outputs – Reviews/Approvals			
Actions – ANDA	2,800	2,800	2,500
Approval Actions - ANDA (both Tentative and Full Approvals)	825	825	825
Median Review Time from ANDA Receipt to Approval (months)	26	26	25
Actions - ANDA Supplementals (Labeling and Manufacturing)	8,400	8,400	8,400
Over-the-Counter Drug Review[1]			
OTC Monographs Under Development	26	14	7
OTC Monographs Published	15	11	4
Best Pharmaceuticals for Children Act			
Labels Approved with New Pediatric Information	16	20	20
New Written Requests Issued	11	12	12
Pediatric Exclusivity Determinations made	9	12	12
Post Exclusivity Safety Report	3	5	4
Patient Safety			
Workload – Submissions/Filings/Requests			
Submissions: Adverse Event Reports	2,503,400	2,678,638	2,866,142
Electronic Submissions: % of Total Adverse Drug Reaction Reports	96%	96%	96%
Electronic Submissions: % of Serious/Unexpected Adverse Drug Reaction Reports	100%	100%	100%
Submissions: Drug Quality Reports	21,000	22,000	23,000
Outputs – Reviews/Approvals			
Safety reviews completed by Office of Surveillance & Epidemiology	8,497	8,667	8,840
Number of drugs with Risk Communications	100	110	120
Administrative/Management Support			
Workload			
Number of Advisory Committee Meetings	15	27	27
Number of FOI Requests	2,324	2,400	2,400
Number of FOI Requests Processed	2,000	2,425	2,425
Number of Citizen Petitions Submitted (excluding suitability petitions and OTC monograph-related petitions)	87	87	76
Number of Citizen Petitions Pending on Last Day of Fiscal year (excluding suitability petitions and OTC monograph-related petitions)	168	168	154
Number of Citizen Petitions Completed (excluding suitability petitions and OTC monograph-related petitions)[2]	107	107	88

[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 30 - CDER Workload and Outputs

Field Human Drugs Program Activity Data (PAD)			
Field Human Drugs Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,064***	***1,432***	***1,432***
Pre-Approval Inspections (NDA)	66	70	70
Pre-Approval Inspections (ANDA)	60	80	80
Bioresearch Monitoring Program Inspections	420	571	571
Drug Processing (GMP) Program Inspections	398	540	540
Compressed Medical Gas Manufacturers Inspections	22	33	33
Adverse Drug Events Project Inspections	52	66	66
OTC Monograph Project and Health Fraud Project Inspections	8	15	15
Compounding Inspections[1]	76	110	110
Domestic Laboratory Samples Analyzed	933	970	970
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***400***	***962***	***962***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	75	92	92
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	96	158	158
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	128	231	231
Foreign Drug Processing (GMP) Program Inspections	127	531	531
Foreign Adverse Drug Events Project Inspections	2	5	5
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,464***	***2,394***	***2,394***
IMPORTS			
Import Field Exams/Tests	5,196	7,140	7,140
Import Laboratory Samples Analyzed	1,078	885	885
Import Physical Exam Subtotal	**6,274**	**8,025**	**8,025**
Import Line Decisions	1,021,775	1,052,428	1,084,001
Percent of Import Lines Physically Examined	0.61%	0.76%	0.74%
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS [5]	***1,464***	***2,394***	***2,394***

[1] The number of compounding inspections includes inspections of compounders that are not registered with FDA as outsourcing facilities.

[2] The FY 2021 actual unique count of foreign inspections includes 34 OGPS inspections (25 for China, 9 for India, and 0 for Latin America).
[3] ORA is currently evaluating the calculations for future estimates.

[4] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.
[5] Count of "Third Party" Foreign Inspections 28 (not included in Overall counts above)

Figure 31 - Field Human Drugs Program Workload and Outputs

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.[65] 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; and
- 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; and Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023.

Allocation Methods: Direct Federal; Intramural

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Biologics	**426,027**	**441,809**	**456,717**	**489,765**	**509,255**	**19,490**
Budget Authority	***252,128***	***254,031***	***259,953***	***271,515***	***277,570***	***6,055***
User Fees	***173,899***	***187,778***	***196,764***	***218,250***	***231,685***	***13,435***
Center	382,468	399,304	410,004	439,629	457,364	17,735
Budget Authority	210,131	212,026	215,127	223,465	228,128	4,663
User Fees	172,337	187,278	194,877	216,164	229,236	13,072
Field	43,559	42,505	46,713	50,136	51,891	1,755
Budget Authority	41,997	42,005	44,826	48,050	49,442	1,392
User Fees	1,562	500	1,887	2,086	2,449	363
FTE	**1,441**	**1,503**	**1,458**	**1,465**	**1,469**	**4**

Figure 32 – Biologics Funding History Table

The FY 2024 President's Budget request for the Biologics Program is $509,255,000 of which $277,570,000 is budget authority and $231,685,000 is user fees. The budget authority increases by $6,055,000 compared to the FY 2023 Enacted Budget. User Fees increase by $13,435,000. The Center for Biologics Evaluation and Research (CBER) amount in the request is $457,364,000. The Office of Regulatory Affairs (ORA) amount is $51,891,000.

The FY 2024 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 respond quickly and creatively to address the COVID-19 pandemic and will continue to prioritize the COVID-19 response in FY 2024 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 presently not commercially viable. CBER will continue to facilitate the development of innovative oncology products including immunotherapies, chimeric antigen receptor T cells (CAR-T) therapies, and cancer vaccines such as the HPV vaccine.

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 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. In addition to protecting the blood supply from infectious disease, CBER aims to improve the availability of vaccines to immunize the public prior to EID exposure, decreasing the number of infections and contamination events. 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, vaccines for emerging infectious diseases, and influenza.

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 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 to harmonize existing regulatory standards and works with international scientific efforts to establish and maintain reference materials and standards for biologics.

BUDGET AUTHORITY

FY 2024 President's Budget: **Biologics** *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Enacted	**223,465**	**48,050**	**271,515**
FY 2024 Budget Authority Changes	**4,663**	**1,392**	**6,055**
Advancing Medical Product Safety	**806**	**-**	**806**
Medical Product Safety Data Modernization	276	-	276
ACT for ALS	530	-	530
Investing in Core Operations - Crosscutting	**8,966**	**2,313**	**11,279**
Enterprise Data and IT Modernization	926	118	1,044
Public Health Employee Pay Costs	7,256	2,070	9,326
OC Regulatory and Mission Support	784	125	909
Other Adjustments	**(5,109)**	**(921)**	**(6,030)**
ORA Transfer to HQ/OGPS	-	(968)	(968)
FDARA Sec. 905 BA Shift	(5,761)	(55)	(5,816)
Comparability Adjustment	652	102	754
FY 2024 Budget Net Total: Biologics	**228,128**	**49,442**	**277,570**

Figure 33 – Biologics Budget Authority

Medical Product Safety: +$806,000 / 2 FTE

ACT for ALS: +$530,000 / 2 FTE

Center: +$530,000 / 2 FTE

The FY 2024 President's Budget request includes an increase of $2.5 million, including $530,000 for CBER to implement ACT for ALS, including implementation of the ACT for ALS Action Plan, operation of the Public Private Partnership, and grant awards under FDA Rare Neurodegenerative Disease Grant Program.

Although activities under the ACT for ALS were mandated by Congress, FDA has not received any direct funding to implement the ACT for ALS. The FY 2024 Budget will provide FDA with initial new resources for implementation, including the ability to issue grants and contracts and hire FTE. With a dedicated source of funding, FDA will begin to implement activities outlined in the ACT for ALS Action Plan. Within CBER, the FTE requested will provide subject matter expertise and facilitation for CBER's work as part of the FDA Rare Neurodegenerative Diseases Task Force, the Public-Private Partnership for Rare Neurodegenerative Diseases, and coordination of regulatory science efforts.

The additional FTE will also provide sustainable support for the medium- and long- term vision of FDA's ACT for ALS Action Plan within CBER, by providing expertise as FDA works collaboratively across its organizations to implement the Science Strategy for ALS. This work will explore gaps in the understanding of ALS natural history, expand collection of patient perspectives, and explore innovative trial designs among other activities outlined in the ACT for ALS Action Plan. In particular, CBER will review its experience with applications for ALS and rare neurodegenerative disorder treatments to identify cross-application safety signals, with a focus on factors such as the specific type of product (e.g., gene therapy, cell therapy, vector), route of administration, and study population (e.g., age, disease severity, clinical manifestations). FDA will use this safety information to inform its advice on the design of subsequent clinical trials for the use of cell and gene therapies to treat ALS and other neurodegenerative diseases.

Medical Product Safety Data Modernization: +$276,000

Center: +$276,000

The FY 2024 President's Budget request includes an increase of $3.0 million for Data Modernization and Enhanced Technologies: Medical Product Safety, to include $276,000 for CBER to accelerate efforts to modernize and streamline review of complex biologics.

A robust information management and data infrastructure that supports regulatory capabilities is critical to managing and reviewing the increased number of novel and scientifically complex biologics, including those to prevent and treat emerging and evolving infectious diseases. These capabilities, enabled by a modern regulatory information management system, can help to address challenging scientific, medical, and regulatory issues and facilitate getting safe and effective vaccines and therapeutics to the public. CBER will use these resources to accelerate efforts to modernize and streamline its review of complex biologics, including using new capabilities and enhanced platforms to capture and share information from submissions and review, and will leverage other FDA capabilities where possible.

CBER has reached a critical juncture in the regulation of biological products, including novel and scientifically complex biologics such as cell and gene therapies, vaccines, and blood products. In recent years, CBER has dramatically increased the overall number of regulatory submissions reviewed. Many of these regulatory submissions to CBER are increasingly incorporating novel data sources including real world evidence, digital health technologies, adaptive clinical trial designs, and genomics and computational biology, which consist of large and complex data sets. This initiative will support CBER in managing its increasingly complex portfolio of biologics, devices and combination products, facilitating improved development and review of novel and complex biologics.

Crosscutting: +$11.3 million / 4 FTE

Public Health Employee Pay Costs: +$9.3 million

Center: +$7.3 million

Field: +$2.0 million

The FY 2024 President's Budget request includes $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTE funded through budget authority. Within the Biologics program, $9.3 million is provided for pay costs, including $7.3 million for CBER and $2.0 million for ORA.

OC Regulatory and Mission Support: +$909,000 / 3 FTE

Center: +$784,000 / 1 FTE

Field: +$125,000 / 2 FTE

The FY 2024 Budget includes $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within Biologics program, $909,000 is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$1.0 million / 1 FTE

Center: +$926,000 / 1 FTE

Field: +$118,000

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $1.0 million for the Biologics program, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

USER FEES

Current Law User Fees: +13.4 million

Center: +$13.1 million

Field: +$363,000

The Biologics Program request includes an increase of $13.4 million for user fees which 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

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) and FDA priorities and new authorities provided through the 21st Century Cures Act. The following selected accomplishments by priority area demonstrate the Biologic 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.[66]

Protecting Public Health Through Scientific Advancement

FDA's Biologics Program 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 and number of product applications will benefit the public greatly, but also requires increasingly more sophisticated regulation 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's commitment supports FDA's public health agenda 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 innovators and developers of advanced manufacturing 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 2022, CBER granted 63 Breakthrough Therapy designations, with 31 of the products being for rare

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

diseases (Orphan designated). FDA granted 79 Regenerative Medicine Advanced Therapy (RMAT) designations since program inception in December 2016 with 34 being for rare diseases. To ensure the availability of FDA-regulated products, CBER works with manufacturers and uses regulatory flexibility and expedited reviews to both prevent and mitigate shortages. In FY 2022, CBER documented one resolved shortage, one new product shortage, 10 prevented shortages, five ongoing shortages, and 27 notifications from 18 different manufacturers.[67]

CBER's regulatory science program addresses knowledge gaps and improves familiarity with how new science and technology are applied to FDA-regulated products. 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 supports development of new tools, models, standards, and methods, harnessing new technologies to expedite product development and provide effective scientific and regulatory responses for public health emergencies. Research is a critical component to advancing CBER's initiatives related to individualized therapies, advanced manufacturing, pathogen reduction, microbiome, and preparedness efforts to bring needed treatments and preventative measures to the public.

CBER supports the Administration's Executive Orders, including Executive Order 13950, "On Advancing Racial Equity and Support for Underserved Communities Through the Federal Government." CBER actively addresses issues to help close the health equity gap, including advancing clinical trial diversity and addressing the needs of populations disproportionately impacted by certain diseases and conditions. In April 2022, CBER worked with other medical product centers to announce the availability of a draft document entitled, "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials" to develop policies and provide recommendations to advance clinical trial diversity. Additionally, to help close these gaps CBER leverages vaccine surveillance systems to assess safety and health outcomes in specific subpopulations. In addition, to facilitate improvement of communication about COVID-19 vaccines, CBER engages with key stakeholders representing underserved populations and the Fact Sheets for Recipients and Caregivers have been translated into more than 25 different languages. CBER also facilitates the development of advanced manufacturing techniques for vaccines and therapeutics to help increase supplies, decrease costs, make treatments commercially viable for small subpopulations, and reduce distribution barriers, such as storage requirements.

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 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 disease, CBER aims to improve the availability of vaccines to immunize the public prior to EID exposure. To this end, CBER's biologics program is committed to expediting the development and evaluation of new products for EIDs and a broad range of complex, life-

[67] 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

threatening and rare diseases, and its demonstrated efforts have increased public health preparedness and response to health security threats.

CBER collaborates with federal partners and other stakeholders, including industry and academia, to monitor and address infectious diseases. Also, many of the products that FDA regulates address infectious disease threats that are not unique to the U.S., and 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 a cornerstone 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 took 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.[68]

Since early May 2022, an outbreak of monkeypox (an orthopoxvirus related to smallpox) has been ongoing in several countries, including the United States. In August 2022, the ongoing spread of the monkeypox virus was declared a Public Health Emergency (PHE) in the United States by the U.S. Department of Health and Human Services. FDA has been collaborating with its federal public health partners, closely tracking reports of monkeypox transmissions in the United States and coordinating preparedness efforts accordingly. JYNNEOS is the only FDA-approved vaccine for the prevention of monkeypox disease. JYNNEOS is also approved for prevention of smallpox disease. It is approved for use in individuals 18 years of age and older who are determined to be at high risk for smallpox or monkeypox infection. JYNNEOS is approved for administration subcutaneously (beneath the skin), as a two-dose series, 4 weeks apart. JYNNEOS is included in the Strategic National Stockpile (SNS). CBER has worked to facilitate the availability of safe and effective monkeypox vaccine doses to the public by expediting the required inspection of the fill-and finish facility. FDA facilitated advance shipments of manufactured doses to the U.S. so that they would be ready to be distributed once the inspection was completed and the manufacturing changes were approved. In addition, in August 2022, CBER issued an Emergency Use Authorization (EUA) for administration of JYNNEOS by the intradermal route, increasing the total number of doses available of the vaccine by up to five-fold. The EUA also allows for use of the vaccine in individuals younger than 18 years of age determined to be at high risk for monkeypox infection; in these individuals JYNNEOS is administered by subcutaneous injection.

Annual influenza vaccination remains the best way to prevent influenza disease and its complications, as well as the impact on hospitalization and healthcare resource utilization. CBER conducts research to increase manufacturing diversity and capacity for influenza vaccine

[68] 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

production. 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. Following that process, FDA convenes its 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. The committee also reviews data about which flu viruses have caused illnesses in the past year, how the viruses are changing, and disease trends for the U.S. FDA takes that information into account before it selects the virus strains for FDA-licensed manufacturers to include in their vaccines for use in the U.S. In March 2022, the VRBPAC recommended the strains for inclusion in the influenza vaccines for the 2022-2023 U.S. influenza season. As an Essential Regulatory Laboratory (ERL) in WHO's Global Influenza Surveillance and Response System (GISRS), CBER contributes to production of vaccine seed stocks and reagents required for manufacture and release of influenza vaccines.

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 October 2022, FDA approved the Boostrix (Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine, Adsorbed [Tdap]) vaccine to be given during the third trimester of pregnancy. Boostrix is the first vaccine approved specifically for use during pregnancy to prevent disease in young infants whose mothers are vaccinated during pregnancy. Boostrix boosts antibodies in the mother, which are then transferred to the developing baby, thereby preventing pertussis in infants younger than two months of age.

Clostridioides difficile (C. difficile) is a bacterium that can cause *Clostridioides difficile* 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. In November 2022, CBER approved REBYOTA, the first fecal microbiota product approved by the agency, for the prevention of recurrence of CDI in individuals 18 years of age and older, following antibiotic treatment for recurrent CDI. The administration of fecal microbiota is thought to facilitate restoration of the gut flora to prevent further episodes of CDI. As the first FDA-approved fecal microbiota product, this is an advance in caring for patients who have recurrent C. difficile infection and represents an important milestone, as it provides an additional approved option to prevent recurrent CDI.

COVID-19 Public Health Emergency

CBER has implemented a focused response on the COVID-19 public health emergency, especially 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 save lives by preventing disease, hospitalizations, and deaths. Given the COVID-19 public health emergency (PHE), COVID-19 vaccines development timelines were greatly shortened without compromising safety and effectiveness standards. Since December 2020, FDA has issued EUAs for four vaccines to prevent COVID-19. FDA issued an EUA for the Novavax COVID-19 Vaccine, Adjuvanted for individuals 18 years of age and older in July 2022. This authorization offers adults in the United States who have not yet received a COVID-19 vaccine an additional vaccine option that meets the FDA's rigorous standards for safety, effectiveness and manufacturing quality needed to support EUA. As of November 2022, CBER had reviewed over 1,700 EUA amendments to authorized COVID-19 vaccines. FDA has licensed (approved)

Comirnaty (Pfizer-BioNTech) for use in individuals 12 years of age and older and Spikevax (Moderna) for use in individuals 18 years of age and older. Both biologics license applications (BLAs) built upon the data and information previously submitted that supported manufacturers' EUAs. To maintain an open and transparent scientific review process, FDA convenes the VRBPAC as warranted to discuss the data pertaining to the safety and effectiveness of COVID-19 vaccines for various populations, including 7 meetings in FY 2022. CBER conducted 32 COVID-19 research studies, which have produced more than 74 publications addressing topics with wide-ranging implications for evaluating antibody and vaccine effectiveness, relevant for COVID-19 and for future vaccine development and regulation.

After the initial vaccine authorizations, FDA continued working to lessen the public health burden caused by the COVID-19 pandemic. FDA has taken action to help protect the American public from the most severe outcomes of COVID-19, such as identifying when additional doses of vaccine would be beneficial. FDA uses the best available science, real-world data, and when warranted, convenes VRBPAC for advice, to amend these authorizations.

Ever since the first SARS-CoV-2 variants began emerging, FDA has been planning for the possibility that the composition of COVID-19 vaccines would need to be changed to address circulating variants and has previously provided guidance to vaccine manufacturers on how to do so efficiently. In June, FDA convened the VRBPAC to publicly discuss whether a change to the vaccine strain composition of COVID-19 vaccines for booster doses would be necessary for the 2022 fall and winter seasons. The committee voted overwhelmingly to include an Omicron component in COVID-19 vaccines for use as a booster dose. On August 31, 2022, FDA issued emergency use authorizations for the Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 18 years of age and older and the Pfizer-BioNTech COVID-19 Vaccine, Bivalent for use as a single booster dose in individuals 12 years of age and older. On October 12, 2022, FDA authorized Pfizer-BioNTech COVID-19 Vaccine, Bivalent and Moderna COVID-19 Vaccine, Bivalent for use as a single booster dose for children ages 5 through 11 years, and 6 years through 17 years, respectively and on December 8, 2022 for use in children 6 months through 5 and 6 years old, respectively. Both vaccines are authorized for use as a single booster dose at least two months following primary or booster vaccination. These bivalent COVID-19 vaccines include an mRNA component corresponding to the original strain to provide an immune response that is broadly protective against COVID-19 and an mRNA component corresponding to the Omicron variant BA.4 and BA.5 lineages to provide better protection against COVID-19 caused by the Omicron variant. In addition, CBER has been actively involved in COVID-19 cluster teleconferences to discuss data needed to authorize COVID-19 vaccines against SARS-CoV-2 variants as well as co-chairing meetings with global regulators to align regulatory strategies on preclinical and clinical testing requirements for SARS-CoV-2 vaccines variants.

The below graphic details the key authorizations, approvals, regulatory actions in FY 2022.

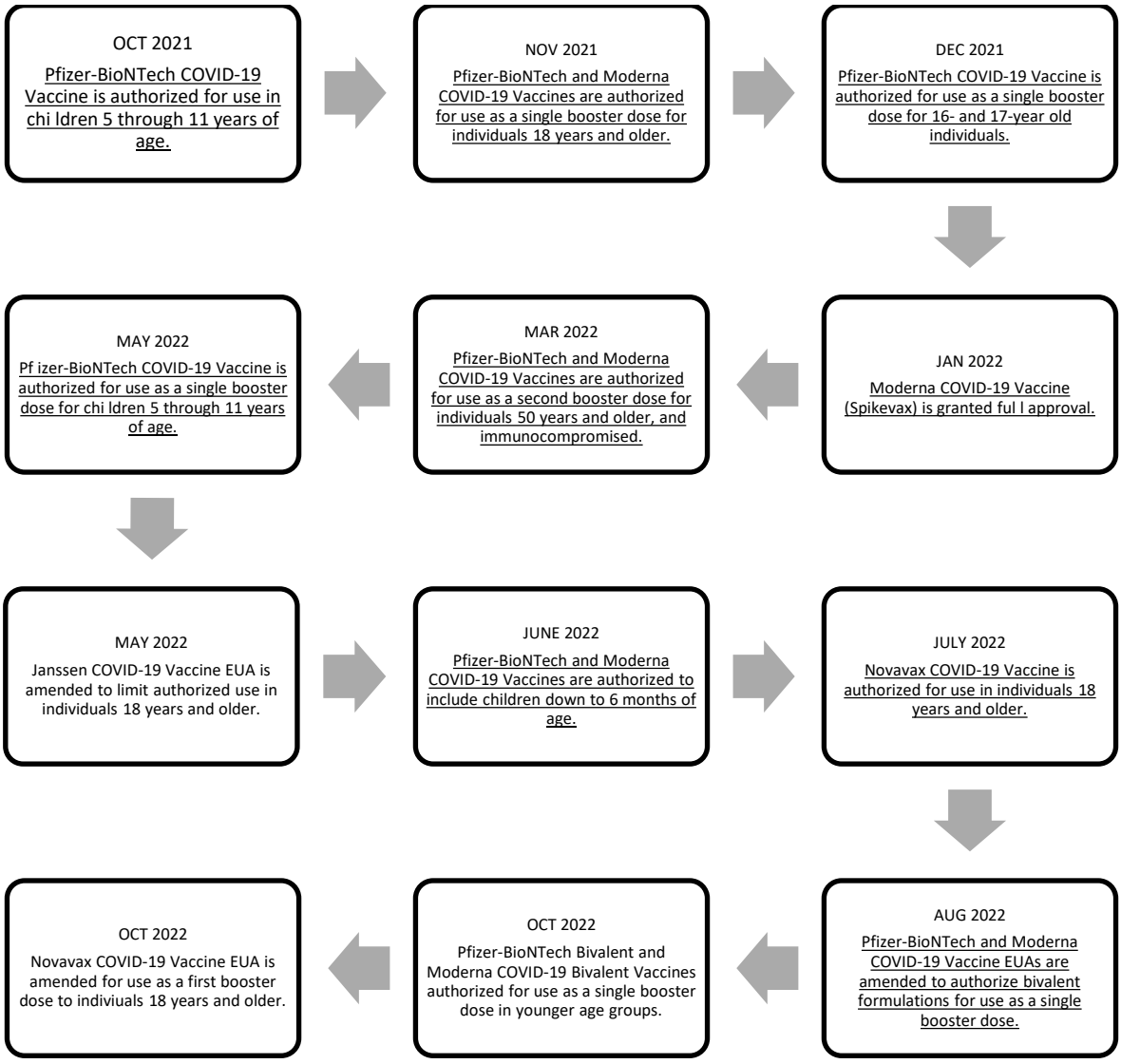

Figure 34 - FY 2022 COVID-19 Key Authorization, Approvals, and Regulatory Actions

Biologics Safety and Pharmacovigilance

CBER continues to track the safety and effectiveness of regulated biological products, including vaccines in the real world. Even very large clinical trials are sometimes too small to detect extremely rare side effects, known as adverse reactions, and clinical trials are not designed to learn about the efficacy of these products in certain populations. Real World Evidence (RWE) represents the clinical evidence for the usage and potential benefits or risks through the analysis of patient health information collected through multiple sources, such as electronic health records (EHR), insurance claims, reports, and public health databases. The 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 are best for which patients.

CBER's Biologics Effectiveness and Safety (BEST) Program leverages a variety of data partners and methods, tools, expertise, and infrastructure to conduct surveillance and 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. BEST has also enabled innovative approaches such as machine learning, artificial intelligence, and natural language processing (NLP) to identify potential serious health outcomes and provide assisted medical chart reviews of EHR to improve FDA's ability to identify cases of serious, life-threatening adverse effects.

FDA closely monitors COVID-19 vaccine safety and is investigating these findings by conducting rigorous epidemiological studies using the comanaged FDA and CDC Vaccine Adverse Event Reporting System (VAERS), 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. Medical claims databases from BEST and the Centers for Medicare & Medicaid Services (CMS) data systems are continuously evaluating 16 potential rare COVID-19 vaccine adverse reactions in data representing more than 120 million people. The robustness of our safety surveillance systems supports our commitment to ensuring that science and data guide our decisions. For example, in April 2021, the FDA and the Centers for Disease Control and Prevention (CDC), announced a recommended pause in administration of the Janssen COVID-19 Vaccine to investigate six reported cases of Thrombosis with Thrombocytopenia Syndrome (TTS). Since then, FDA conducted an updated analysis and determined that the risk of TTS, a syndrome of rare and potentially life-threatening blood clots in combination with low levels of blood platelets with onset of symptoms approximately one to two weeks following administration of the Janssen COVID-19 vaccine, warranted limiting the authorized use of the vaccine.

FDA finalized "The COVID-19 Vaccine Safety Surveillance: Active Monitoring Master Protocol" in February 2021. The primary objective of this protocol is to monitor the rates of various adverse events of special interest (AESIs) following COVID-19 vaccination in near real-time following authorization or licensure. Addendums for the protocol were added in April 2022 for the pediatric population and for following third or booster dose administration among a commercially insured population aged 18-64 years and the Medicare population aged 65 years and older in May 2022.

Lancet published an FDA-authored article entitled, "Risk of myocarditis and pericarditis after the COVID-19 mRNA vaccination in the USA: a cohort study in claims databases" in June 2022. This publication used the BEST Program to indicate the risk of myocarditis or pericarditis events in people who received COVID-19 mRNA vaccines was elevated in younger populations; however, the incidence was rare. The study showed that, in the period of 1–7 days after receipt of the second dose, the highest risk was in men aged 18–25 years. A head-to-head comparison of myocarditis and pericarditis risk for the mRNA-1273 and BNT162b2 vaccine brands did not

indicate a statistically significant difference, but also could not rule out that a difference might exist. In July 2022, the BEST Program posted the "BETTER: Bayesian Evaluation of Time-To-Event and Reliability (for vaccine surveillance) Research Protocol." The goal of this protocol is to expand FDA's use of innovative approaches to evaluating vaccine safety by comparing the performance of a Bayesian testing framework with the current standard approach, in terms of both the hypothesis testing errors (sensitivity and specificity) and accuracy in estimating the relative risks of adverse events of interest.

Maintaining a 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. The blood supply is safer than it has ever been. While blood and blood products may always carry an inherent risk of infectious agents, CBER aims to reduce the risk to the lowest level reasonably achievable while ensuring an adequate blood supply. CBER works closely with other parts of the DHHS to identify and respond to potential threats to blood safety, to develop safety recommendations, to monitor the blood supply and help industry promote the importance of blood donation, and to collaborate with other government and non-government partners. Internationally, CBER serves on the WHO Advisory Group for Blood Regulation, Availability and Safety, a forum for international blood regulatory authorities to share insights and support policies and strategies to strengthen blood systems, and advance global access to safe, effective and quality-assured blood products.

FDA is committed to ensuring a safe and adequate blood supply. The Transfusion Transmissible Infections Monitoring System (TTIMS), a collaborative effort with the National Heart, Lung, and Blood Institute and the HHS Office of the Assistant Secretary of Health, 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 HIV, hepatitis B virus, and hepatitis C virus incidence and prevalence. In February 2022, TTIMS received approval to revise the risk factor questionnaire survey to add donors who test positive for syphilis and include additional donors testing positive for the hepatitis B virus. The scientific data collected through such interview-based risk factor elicitation of blood donors is used to monitor and help ensure the safety of the United States blood supply.

In December 2022, CBER published updated guidance with recommendations to reduce the risk of transfusion-transmitted malaria (TTM). The recommendations contained in this guidance apply to the collection of Whole Blood and blood components, except Source Plasma. This guidance supersedes the guidance titled "Revised Recommendations to Reduce the Risk of Transfusion-Transmitted Malaria; Guidance for Industry" dated from April 2020, and will remain in effect outside of the context of the public health emergency related to COVID-19.

Additionally, in May 2022, CBER published a guidance with revised recommendations to reduce the possible risk of transmission of Creutzfeldt-Jakob Disease and Variant Creutzfeldt-Jakob Disease by blood and blood components. Based on available data, CBER removed recommendations to indefinitely defer blood donors with specific geographic risks and donors who had received blood transfusions in certain countries, thereby increasing the number of eligible blood donors while maintaining the safety of the blood supply.

The Agency remains committed to considering alternatives to the time-based deferrals currently in place for MSM that are based on scientific data and that will maintain a high level of blood

safety. FDA sponsored the Assessing Donor Variability and New Concepts in Eligibility (ADVANCE) pilot study, intended to evaluate individual risk assessment as an alternative to time-based deferrals for men who have sex with men (MSM). FDA reviewed the data from this study to assess the feasibility and safety of alternative donor eligibility policies to reduce the risk of HIV transmission by blood and blood components.

Based on its review of the totality of the available evidence, in January 2023, CBER published the draft guidance titled "Recommendations for Evaluating Donor Eligibility Using Individual Risk-Based Questions to Reduce the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products." This draft guidance, when finalized, will supersede the guidance entitled, "Revised Recommendations for Reducing the Risk of Human Immunodeficiency Virus Transmission by Blood and Blood Products" dated April 2020, and updated in August 2020.

Pathogen reduction technologies can address the infectious risk from viral, bacterial, and parasitic pathogens, potentially covering emerging infectious diseases as well as the known transfusion transmitted infections which are of concern for the blood supply. CBER is working with a variety of different partners to support innovative pathogen reduction technologies for blood safety from infectious disease-causing pathogens. Projects include funding external research programs to advance new technologies for pathogen reduction in whole blood and developing an internal pathogen reduction research program. In response to specific questions from blood establishments, CBER issued a guidance addressing the manufacture of blood components using a pathogen reduction device in blood establishments in November 2021.

Cell and Gene Therapy and Rare Diseases

Cell and gene therapy holds considerable potential for the treatment of hereditary genetic disorders, including rare, neurodegenerative, and infectious diseases. The number of cell and gene therapy submissions is rising sharply and is expected to continue in the near future. More than 200 new gene therapy INDs are coming to CBER annually, up sharply from just over 100 in FY 2017. CBER has been supporting the fast pace of products advancing in clinical development, with an increasing number yielding marketing applications.

A full list of CBER product approvals may be found at FDA's website: Biological Approvals. Recent key approvals include:

- ADSTILADRIN (nadofaragene firadenovec-vncg), the first gene therapy for the treatment of adults of 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)
- HEMGENIX (etranacogene dezaparvovec-drlb), the first gene therapy for the treatment of adults with Hemophilia B, who currently use Factor IX prophylaxis therapy, have current or historical life-threatening hemorrhage, or have repeated, serious bleeding episodes (November 2022)
- SKYSONA (elivaldogene autotemcel), a stem cell-based gene therapy indicated to slow the progression of neurologic dysfunction in boys 4-17 years of age with early, active cerebral adrenoleukodystrophy (CALD) (September 2022)
- ZYNTEGLO (betibeglogene autoemcel), the first stem cell-based gene therapy indicated for treatment of adult and pediatric patients with β-thalassemia who require regular red blood cell (RBC) transfusions (August 2022)

- CARVYKTI (ciltacabtagene autoleucel), a type of CAR-T cell therapy indicated for treatment of adults with relapsed or refractory multiple myeloma, after four or more prior lines of therapy (February 2022).

CBER provides extensive scientific and regulatory advice to product manufacturers throughout the medical product lifecycle. Advice starts at the INTERACT and/or pre-IND stage 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 the FDA's interpretation of, or policy on, 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:

- Final Guidance for Industry: Human Gene Therapy for Neurodegenerative Diseases (FDA-2020-D-2101), which provides recommendations to sponsors developing human gene therapy products for neurodegenerative diseases affecting adult and pediatric patients (October 2022)
- Draft Guidance for Industry: Considerations for the Development of Chimeric Antigen Receptor (CAR) T Cell Products (FDA-2021-D-0404), which provides recommendations to sponsors developing chimeric antigen receptor (CAR) T cell products (March 2022)
- Draft Guidance for Industry: Human Gene Therapy Products Incorporating Human Genome Editing (FDA-2021-D-0398), which provides recommendations to sponsors developing human gene therapy products incorporating gene editing of human somatic cells (March 2022)

CBER continues to engage with stakeholders on topics on the cutting edge of medicine and drug development. CBER held its annual patient engagement and regenerative medicine meeting in May 2022 to bring together patients, caregivers, advocates, and other stakeholders to discuss ways for patients and their advocates to help advance regenerative medicine treatments such as cell and gene therapy. CBER also continues to facilitate the development of innovative oncology products including immunotherapies, CAR-T cell therapies, and cancer vaccines such as the HPV vaccine.

There is significant unmet need for rare disease populations, which often are vulnerable and underserved given the challenges in accessing medical care and treatment. CBER's Rare Disease Program facilitates advancing development of CBER-regulated biological products for rare diseases through supportive activities and active collaboration with rare disease partners from across the Agency. Additionally, CBER is co-lead with the Foundation for the National Institutes of Health (FNIH) and the National Center for the Translational Sciences (NCATS) for the Bespoke Gene Therapy Consortium (BGTC) which is a public-private partnership focused on utilizing a consortium framework and a common set of procedures in a pre-competitive environment to drive innovation and promote access to individualized 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 presently not commercially viable.

CBER is also promoting global convergence on regulation of cell and gene therapy products and has a leading role in drafting a WHO document on development of a regulatory framework for these products. CBER chaired a WHO consultation in February 2022, with engagement of global stakeholders, to discuss issues important for providing adequate regulatory oversight for different types of cell and gene therapy products.

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 2022 include the issuance of four Untitled Letters for marketing of unapproved regenerative medicine products and five Warning Letters for unapproved and/or adulterated regenerative medicine products to treat various diseases or conditions.

Advanced Manufacturing

FDA encourages development and adoption of advanced manufacturing technologies to support processes with fewer interruptions in production, fewer product failures, and greater assurance that the biologic products manufactured will provide the expected clinical performance. The CBER Advanced Technologies Team offers pre-submission regulatory support to meet with prospective innovators and developers of advanced manufacturing technologies to provide informal consultation during early stages of development. CBER also works closely with the Office of Regulatory Affairs (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 15 scientific publications. Through 21st Century Cures Innovation Account (CURES), CBER issued nine new grants related to advanced manufacturing of biological products, and continued funding for the manufacturing of Adeno-associated virus (AAV) vectors to help advance the development of therapies for diseases affecting very small populations. An earlier CURES award resulted in the development of an advanced version of Freeform Reversible Embedding of Suspended Hydrogels (FRESH) technology, to 3D print collagen. This technology will help to transform medicine by manufacturing human tissues for organ transplant, drug discovery, and surgical repair using 3D bioprinting.

Using American Rescue Plan (ARP) funding, CBER launched a demonstration project for mRNA vaccine manufacturing, which will focus on best practices in integrated and continuous vaccine manufacturing. Messenger RNA (mRNA) vaccines have emerged as a powerful technology. These vaccines have several advantages, including the major appeal of redesigning vaccine antigens relatively easily to target new diseases or new variants. Still, these vaccines present several new unique manufacturing challenges, such as the need for suitable delivery vehicles (such as lipid nanoparticles), cold storage, and reliance on specialized materials. Production of these and other vaccines may benefit from several advanced manufacturing techniques. For example, distributed manufacturing in decentralized or mobile units could allow vaccines to be produced near the site of distribution, thus reducing the cost and risks of transportation and cold-chain management. This work may also be relevant for multiple types of vaccines, including influenza and other pathogens.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
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 2021: 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 2021:100% Target 90% (Target Exceeded)	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 2021: 100% Target 100% (Target Exceeded)	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 2021: 100% 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 2021: 100% Target: 60% (Target Exceeded)	60%	60%	Maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2022: Continued evaluation of new methods to produce high-yield influenza vaccine reference	Continue evaluation of new methods to produce more stable high-yield	Continue evaluation of new methods to produce more stable high-yield	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
	strains. (Target Met)	influenza vaccine reference strains and improve current manufacturing processes	influenza vaccine reference strains and improve current manufacturing processes	
231301: Percentage of Lot Distribution Reports that were entered into the Regulatory Management System - Biologics License Applications (RMS-BLA) within 7 Days. (Output)	FY 2022: 96% 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 2022: 96.7% 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 2022: 92.9% Target: 65% (Target Exceeded)	65%	65%	Maintain

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

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 2022, FDA met the target to continue evaluation of new methods to produce high-yield influenza vaccine reference strains. 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. A new international collaborative study, designed to compare several

alternative potency methods and evaluate their potential to quantify sub-potent vaccine using a variety of stress methods, was completed in FY2022.

- An H5N8 candidate vaccine virus for a recently identified H5N8 influenza virus with pandemic potential that was generated in FY2021 was further characterized and listed on the WHO website for interested manufacturers.
- Demonstrated that candidate vaccine viruses for influenza viruses with pandemic potential (e.g., 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 a candidate vaccine virus engineered for higher NA antigen content could provide protection in animal models with a lower vaccine dose. Continued collaborations with the NIH Vaccine Research Center to assist in producing recombinant NA for vaccines and for measuring NA responses from individuals in clinical trials.
- Continued development of new methods to purify and quantify NA in vaccine candidates. Including a 3-step method for purifying soluble NA vaccine antigens produced using insect cells.

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 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
Original Biologics License Applications (BLA)			
Workload [1]	22	22	22
Total Decisions [2]	14	14	14
Approved	12	12	12
BLA Efficacy Supplements			
Workload [1]	23	23	23
Total Decisions [2]	19	19	19
Approved	15	15	15
BLA Manufacturing Supplements			
Workload [1]	1,279	1,279	1,279
Total Decisions [2]	1,321	1,321	1,321
Approved	1,255	1,255	1,255
BLA Labeling Supplements			
Workload [1]	124	124	124
Total Decisions [2]	136	136	136
Approved	127	127	127
Original New Drug Application (NDA)			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
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]	25	25	25
Total Decisions [2]	12	12	12
Approved	12	12	12
NDA Labeling Supplements			
Workload [1]	1	1	1
Total Decisions [2]	3	3	3
Approved	2	2	2
Original Abbreviated New Drug Application (ANDA)			
Workload [1]	0	0	0
Total Decisions [2]	1	1	1
Approved	1	1	1
ANDA Efficacy Supplements			
Workload [1]	0	0	0
Total Decisions [2]	0	0	0
Approved	0	0	0

Figure 35 - CBER Workload and Outputs 1 / 2

Biologics Program Activity Data (PAD)			
CBER Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
ANDA Manufacturing Supplements			
Workload [1]	8	8	8
Total Decisions [2]	6	6	6
Approved	6	6	6
ANDA Labeling Supplements			
Workload [1]	1	1	1
Total Decisions [2]	0	0	0
Approved	0	0	0
Device 510Ks			
Workload [1]	37	37	37
Total Decisions [2]	38	38	38
Final Decision - SE	28	28	28
Device Premarket Applications (PMA)[6]			
Workload [1]	5	5	5
Total Decisions [2]	0	0	0
Approved	0	0	0
Device Premarket Applications (PMA) Supplements [7]			
Workload [1]	66	66	66
Total Decisions [2]	85	85	85
Approved	25	25	25
Investigational New Drugs (IND)			
Receipts: IND (new)	819	819	819
Receipts: IND Amendments	18,621	18,621	18,621
Total Active IND [3]	3,844	3,844	3,844
Investigational Device Exemptions (IDE)			
Receipts: IDE (new)	22	22	22
Receipts: IDE Amendments	321	321	321
Total Active IDE [3]	98	98	98
Patient Safety			
Adverse Event Reports Received [4]	809,125	850,000	850,000
Biological Deviation Reports Received	15,010	15,600	15,600
Sponsor Assistance Outreach			
Meetings	749	749	749
Final Guidance Documents [5]	38	40	40
Admin/Management Support			
Advisory Committee Meetings Held	14	15	12
FOI Requests Processed	471	500	525

[1] Workload includes applications received and filed.

[2] Total Decisions include approved, denied, withdrawn, approvable, approvable pending inspection, not approvable, exempt, major deficiency, substantially equivalent (SE), not substantially equivalent (NSE), de novo and complete response (CR).

[3] Total Active includes investigational applications received and existing applications for which CBER has received at least one amendment (IND) or supplement (IDE) during the FY being reported.

[4] Includes MedWatch, Foreign reports and VAERS reports. Does not include Fatality Reports for blood tansfusions or blood collection (under 21CFR606.170) or Medical Device Reports for CBER-regulated medical devices.

[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 36 - CBER Workload and Outputs 2 / 2

Field Biologics Program Activity Data (PAD)			
Field Biologics Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,221***	***1,601***	***1,601***
Bioresearch Monitoring Program Inspections	152	107	107
Blood Bank Inspections	489	689	689
Source Plasma Inspections	160	206	206
Pre-License, Pre-Market Inspections	32	69	69
GMP Inspections	28	40	40
GMP (Device) Inspections	8	10	10
Human Tissue Inspections	375	517	517
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***41***	***59***	***59***
Bioresearch Monitoring Program Inspections	7	10	10
Foreign Human Tissue Inspections	0	1	1
Blood Bank Inspections	7	7	7
Pre-License, Pre-market Inspections	1	5	5
GMP Inspections (Biologics & Device)	23	33	33
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,262***	***1,660***	***1,660***
IMPORTS			
Import Field Exams/Tests	112	97	97
Import Line Decisions	64,884	138,929	140,318
Percent of Import Lines Physically Examined	0.17%	0.07%	0.07%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,262***	***1,660***	***1,660***

[1] ORA is currently evaluating the calculations for future estimates.

[2] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 37 - Field Biologics Program Workload and Outputs

ANIMAL DRUGS AND FOODS

PURPOSE STATEMENT

The Animal Drugs and Foods Program began more than 50 years ago, in 1968, with an amendment to the Federal Food, Drug, and Cosmetic (FD&C) Act to include new authorities for regulating animal drugs and animal food. The 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 from a One Health perspective 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 2018 (P.L. 113-14); Animal Generic Drug User Fee Reauthorization Act of 2018 (P.L. 113-14).

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Final	FY 2022 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Animal Drugs and Foods	**234,507**	**238,847**	**255,973**	**288,353**	**313,958**	**25,605**
Budget Authority	***190,854***	***192,352***	***202,535***	***230,093***	***257,689***	***27,596***
User Fees	***43,653***	***46,495***	***53,438***	***58,260***	***56,269***	***-1,991***
Center	165,361	169,707	182,056	204,730	226,914	22,184
Budget Authority	122,099	123,599	130,111	148,141	172,423	24,282
User Fees	43,262	46,108	51,945	56,589	54,491	-2,098
Field	69,146	69,140	73,917	83,623	87,044	3,421
Budget Authority	68,755	68,753	72,424	81,952	85,266	3,314
User Fees	391	387	1,493	1,671	1,778	107
FTE	**1,011**	**1,061**	**1,023**	**1,066**	**1,131**	**65**

Figure 38 - Animal Drugs and Foods Funding History Table

The FY 2024 President's Budget for the Animal Drugs and Foods Program is $313,958,000 of which $257,689,000 is budget authority and $56,269,000 is user fees. The budget authority increases by $27,596,000 compared to the FY 2023 Enacted Budget. User Fees decreases by $1,991,000. The Center for Veterinary Medicine (CVM) amount in the request is $226,914,000. The Office of Regulatory Affairs amount is $87,044,000.

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. The Center is responsible for all stages of the total product lifecycle, including:

- evaluating new animal drugs for safety, effectiveness, and manufacturing quality
- monitoring animal drugs, animal foods, and animal devices for safety and taking appropriate action to mitigate unsafe or violative products on the market
- evaluating animal food additives for safety and utility
- conducting applied research to further scientific understanding and support data-based decision making to protect human and animal health
- working to prevent and respond to human and animal health emergencies
- developing and implementing policies to combat antimicrobial resistance

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 2018.

These activities and the initiatives requested in the FY 2024 Budget request support mission critical activities, and Presidential, HHS, and FDA human and animal health priorities.

BUDGET AUTHORITY

FY 2024 President's Budget: Animal Drugs and Foods *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Enacted	**148,141**	**81,952**	**230,093**
FY 2024 Budget Authority Changes	**24,282**	**3,314**	**27,596**
Enhancing Food Safety, Nutrition & Cosmetics	**11,903**	**1,406**	**13,309**
New Era of Smarter Food Safety	8,128	-	8,128
Animal Food Safety Lifecycle	3,775	1,406	5,181
Advancing Medical Product Safety	**4,739**	**-**	**4,739**
Postmarket Safety Collaborative	3,000	-	3,000
Medical Product Safety Data Modernization	1,739	-	1,739
Investing in Core Operations - Crosscutting	**6,249**	**3,014**	**9,263**
Enterprise Data and IT Modernization	277	165	442
Public Health Employee Pay Costs	5,635	2,679	8,314
OC Regulatory and Mission Support	337	170	507
Other Adjustments	**1,391**	**(1,106)**	**285**
ORA Transfer to HQ/OGPS	-	(1,452)	(1,452)
Comparability Adjustment	1,391	346	1,737
FY 2024 Budget Net Total: Animal Drugs and Foods	**172,423**	**85,266**	**257,689**

Figure 39 - Animal Drugs and Foods Budget Authority

Food Safety: $13.3 million / 55 FTE

New Era of Smarter Food Safety: +$8.1 million / 34 FTE

Center: +$8.1 million / 34 FTE

The FY 2024 Budget provides $37.0 million for the New Era of Smarter Food Safety, including an increase of $8.1 million for CVM. Science, industry practices and supply chains continue to evolve at a rapid rate, and it is imperative that FDA continues to transform and modernize existing FSMA and food safety programs (see Animal Food Safety Lifecycle below) to keep pace with these changes.

With this increase, CVM will increase its foundational capacity to participate in New Era activities, while exploring the emerging direct to consumer market, potential hazards of these foods, and oversight mechanisms, as animal food sold through these markets are not subject to the FSMA Preventive Controls for Animal Food regulation. CVM will also address knowledge gaps about the animal food supply chain, food safety culture, and behaviors in the animal food industry that can influence the safety of the animal food supply. As the Foods Program begins to create additional tools for inspections, machine learning, and pathogen tracking, CVM will need to ensure it has the capacity to support these activities and ensure advancements for programs, technologies, and policies being developed for human food safety can be adapted or are suitable to meet the needs of the oversight of the animal food industry.

Animal Food Safety Lifecycle: +$5.2 million / 21 FTE

Center: +$3.8 million / 16 FTE

Field: +$1.4 million / 5 FTE

The FY 2024 Budget provides $5.2 million for Animal Food Safety Lifecycle, including $3.8 million for CVM and $1.4 million for ORA, to help address FDA's continued challenge to keep pace with innovative and novel technologies being used to develop animal food ingredients, while addressing foundational gaps in the oversight of the animal food industry as these ingredients are combined, packaged, and sold as animal food.

With this funding, CVM will increase its scientific expertise to conduct pre-market animal food ingredient reviews and provide new consultations on biotechnology plants. CVM will also partner with the Foods Program to develop guidance and prepare for submissions associated with new gene editing technologies. New claims and technology allow industry to advance agriculture and trade in both domestic and international markets. FDA is striving to keep pace with the advancements made by the animal food industry as submissions of innovative new animal food ingredients are more complex and have more data in their submissions.

As CVM works to keep pace with its pre-market review of animal food ingredients, it remains hampered by foundational gaps in its oversight of animal food safety as these products make their way into the market. With this increase, CVM will also move the animal food post-market oversight program closer to the full implementation of FSMA that Congress envisioned by updating inspection and enforcement programs and updating and managing animal food risk models to promote advancements in food safety based on risk and identified food safety gaps. These activities will advance efforts to build an integrated partnership that enables FDA and states with comparable regulatory public health systems to achieve domestic mutual reliance.

Medical Product Safety: $4.7 million / 10 FTE

Postmarket Safety Collaborative: +$3.0 million / 10 FTE

Center: +$3.0 million / 10 FTE

The FY 2024 Budget includes an increase of $10.1 million for Postmarket Safety Collaborative, including $3.0 million for CVM, to enhance safety surveillance and oversight programs and to develop more efficient and effective detection, evaluation, prevention, and mitigation of adverse events. Protecting the health of humans and animals requires FDA to continuously enhance its safety surveillance and oversight programs, consistent with advances in the science of drug and device safety.

With this increase, CVM will bolster its capacity to actively monitor animal drugs marketed in the U.S. for potential safety issues, and modernize its safety signal detection system to identify, analyze and mitigate any serious issues that may result in harm to humans or animals. The funds will also be used to develop a comprehensive integrated compliance program for compounded animal drugs. CVM will conduct targeted outreach and education to help ensure veterinarians have continued access to the compounded animal drugs needed to treat the wide diversity of animals and disease conditions when no FDA-approved or indexed drugs are medically appropriate. CVM has the largest animal adverse event database in the world, with adverse events reported in more than 95,000,000 food animals, and approximately 1,016,000 companion

animals; unfortunately, CVM currently has the capacity to review only 25% of the postmarket safety information for all actively marketed animal drug products and lacks the capacity to respond to all but the most critical safety signals.

Medical Product Safety Data Modernization: +$1.7 million

Center: +$1.7 million

The FY 2024 Budget includes an increase of $3.0 million for Medical Product Safety Data Modernization, to include $1.7 million for CVM. With this increase, CVM will modernize outdated and disparate IT systems and business processes to increase efficiency and effectiveness, reduce overall costs and provide the flexibility needed to meet the challenges of an evolving regulatory landscape. CVM currently lags behind the industries it regulates and its information technology infrastructure is currently founded on the digitalization of paper-based processes and antiquated systems that are significantly outdated. The health of humans and animals are intrinsically linked and updates to our IT infrastructure are critical to position CVM to actively monitor animal food and drug products marketed in the U.S. for potential safety issues, and to quickly identify, analyze and mitigate any serious issues that may result in harm to humans or animals.

Crosscutting: $9.3 million / 3 FTE

Public Health Employee Pay Costs: +$8.3 million

Center: +$5.6 million

Field: +$2.7 million

The FY 2024 Budget includes $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTE funded through budget authority. Within the Animal Drugs and Foods program, $8.3 million is provided for pay costs.

OC Regulatory and Mission Support: +$507,000 / 3 FTE

Center: +$337,000 / 1 FTE

Field: +$170,000 / 2 FTE

The FY 2024 Budget includes $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within the Animal Drugs and Foods program, $507,000 is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$442,000 million

Center: +$277,000

Field: +$165,000

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $442,000 for Animal Drugs and Foods program, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical

Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

USER FEES

Current Law User Fees: -$2.0 million

Center: -$2.1 million

Field: +$90,000

The Animal Drugs and Foods Program includes a decrease of -$2.0 million for user fees which 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

CVM uses a One Health approach to protect and promote the health of humans and animals including food-producing and companion animals. The Center's responsibilities encompass all stages of the animal product lifecycle, including:

- ensuring safety and effectiveness of animal drugs for approval,
- fostering innovation and emerging technologies in animal drugs,
- conducting animal drug preapproval inspections,
- reviewing food additives for safety and utility, and
- ensuring animal food is safe, made under sanitary conditions, and properly labeled.

Pharmacovigilance is also a critical part of the animal drug lifecycle. The safety profile of an animal drug evolves as it is used on a larger population of animals, with issues like drug interactions and medication errors. CVM monitors the safety of drugs used in animals, the safety of humans exposed to animal drugs, and the effectiveness of approved and compounded animal drugs through a pharmacovigilance system. The public depends on CVM to actively monitor the safety and effectiveness of animal drugs, and the safety of animal food, and to quickly identify, analyze and mitigate any serious issues that may result in harm to humans or animals.

Comprehensive risk-based oversight of the animal food supply is also vital to protecting the health of both humans and animals. CVM continues prevention-focused efforts under the FDA Food Safety Modernization Act (FSMA) by working to modernize its science- and risk-based animal food safety system through the establishment of and compliance with preventive control standards to protect human and animal health. 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 and communication systems.

CVM continues to champion efforts to combat antimicrobial resistance, a major national and worldwide public health issue as approximately two million people are infected with antibiotic resistance bacteria each year. The Center is committed to advancing antimicrobial stewardship in veterinary settings, reducing misuse of antimicrobial drugs, and slow the rising threat of resistance, while enhancing the monitoring for the presence of resistant bacteria in retail meats

and other commodities through the National Antimicrobial Resistance Monitoring System (NARMS). CVM's Veterinary Laboratory Investigation and Response Network (Vet-LIRN) also supports 47 state and university veterinary diagnostic laboratories that assist FDA by conducting surveillance of antimicrobial resistance in companion animals and by investigating potential problems with animal drugs, animal food, including pet food, and responding to public health emergencies.

The Center is in a regulatory landscape where industry is utilizing enhanced technology and innovative approaches to do its work and internal agency investments are needed to maintain mission related relevancy. CVM conducted a comprehensive evaluation of how it conducts business with stakeholders in the digital world and begun re-engineering its mission-critical business processes and their corresponding Information Technology (IT) systems to evolve its digital footprint in order to sustain and improve its ability to protect human and animal health. CVM is partnering with FDA's Office of Digital Transformation 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.

Animal Drug Lifecycle

CVM continues to evaluate new animal drug submissions and determines whether animal drug products are safe and effective for their intended use, manufactured to meet current good manufacturing practice requirements and properly labeled. These activities increase the availability of safe and effective animal drug products to support the health of all animals, while ensuring that food from treated food-producing animals is safe for people to eat. More information about recent animal drug product approvals can be found on FDA's website.

These evaluations are supported by CVM's Office of Applied Science as it conducts method trials and develops alternative methods to replace, reduce or refine the need for animal testing. For example, CVM is currently analyzing data from a minimally invasive, non-terminal study in beagles to validate laboratory-based methods to determine if different formulations of drugs are safe and effective, thereby reducing the number of dogs needed for these assessments in industry studies. CVM also undertook a comprehensive program to actively socialize the dogs enrolled in the study, facilitating their transition to their retirement as pets. All of the dogs in the study were subsequently placed directly into safe and permanent homes.

CVM monitors the animal drug supply chain and solicits voluntary information from animal drug sponsors to ascertain, as early as possible, any shortage or potential shortage that is likely to lead to a disruption in the availability of animal drugs or their components in the United States. The public also 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 has developed and continues to improve upon scientific approaches and necessary tools to efficiently and effectively detect, evaluate, prevent, and mitigate adverse events with the current resources available.

Fostering Innovation in Biotechnology and Animal Drugs

Promising new technologies, such as animal biotechnology, have the potential to improve human and animal health, animal welfare, nutrition, and food safety. For example, it is reported that intentional genomic alterations (IGAs) are being developed to make animals less susceptible to diseases, such as porcine reproductive and respiratory syndrome and avian influenza. Developers are also working to address the global organ shortage by developing IGAs in pigs that reduce immunogenicity for use as sources of tissues and organs for xenotransplantation. These innovations present CVM with the opportunity to foster a risk- and science-based program that provides flexibility in the regulatory process to support the development of significant and beneficial technology, while safeguarding human and animal health.

As of November 30 2022, there are 48 products enrolled in the Veterinary Innovation Program (VIP), which offers technical assistance to developers of innovative veterinary products to provide greater regulatory predictability, reduce overall time to approval, and enable early, sustained interactions with innovators. In June 2022, CVM announced new resources for people interested in the development of IGAs in animals, including an on-demand webinar about the agency's first low-risk determination for an IGA in an animal for food use; CVM made the low-risk determination for the marketing of products, including food, from two genome-edited beef cattle and their offspring after determining that the IGA does not raise any safety concerns. The Center has previously made low-risk determinations and decisions to exercise enforcement discretion for many other IGAs in animals for non-food uses and also has approved applications for five IGAs: in groups of goats, chicken, salmon, rabbit and, most recently, in a line of pigs.

Increasing Availability of Safe and Effective Animal Drugs

The Animal Drug User Fee Act (ADUFA) and Animal Generic Drug User Fee Act (AGDUFA) supplement the appropriated budget authority portion of the new animal drug review processes to support timeliness and predictability of pioneer and generic new animal drug reviews. CVM met or exceeded its ADUFA and AGDUFA performance commitments in the current reporting year.

CVM also provides additional approval pathways and incentives to help make more animal drugs legally available to veterinarians and animal owners for use in minor animal species and to help provide veterinarians with legally marketed new animal drugs to fill some treatment gaps for serious or life-threatening diseases or conditions in major species (horses, dogs, cats, cattle, pigs, turkeys, and chickens). One approval pathway for these Minor Use and Minor Species (MUMS) drugs is called conditional approval; the conditional approval is valid for up to five years and allows the drug company to legally sell the animal drug before proving it meets the "substantial evidence" standard of *effectiveness* for full approval. Drug *safety* must have been demonstrated to the full approval standard and the drug must have already achieved a "reasonable expectation of effectiveness." If the drug fails to demonstrate substantial evidence of effectiveness at the end of five years, it is removed from the market.

As part of the ADUFA reauthorization in 2018, Congress expanded CVM's authority to grant conditional approval to include certain animal drugs for use in major species (horses, dogs, cats, cattle, pigs, turkeys, and chickens) for some diseases or conditions that were not previously eligible. As of November 30, 2022, CVM has received 29 requests for expanded conditional approval eligibility, determined that 19 of those requests were eligible and has conditionally approved 3 drugs. On November 15, 2022, CVM conditionally approved Panoquell-CA1, the

first drug to manage the signs of acute onset pancreatitis in dogs. Expanded conditional approval has the potential to incentivize drug development and provide veterinarians with legally marketed new animal drugs to fill treatment gaps for serious or life-threatening diseases or conditions.

Since passage of the Minor Use & Minor Species Animal Health Act in 2004, CVM has administered incentive programs for companies seeking new animal drug approvals for minor uses and minor species. Incentives are needed since the small size of these markets does not provide sufficient return on investment for sponsors seeking FDA approval. MUMS "Designation" status is an incentive that gives sponsors eligibility to apply for grants to help defray the cost of their studies and provides seven years of exclusive marketing rights. Since the MUMS Designation program began in 2009, CVM has provided more than $6.6 million in grant funding in support of 67 MUMS studies. FDA granted 165 MUMS drug "Designations" status and contributed to the approval of 27 drugs ranging from antiparasitic drugs for sheep and goats, to drugs to treat 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. It authorized 16 products for legal marketing for these underserved populations, including the first analgesic drug formulated and marketed specifically for laboratory rodents. The number of drugs entering the indexing process is increasing due, in part, to a recent expansion of eligibility.

CVM also continues to work with other government agencies and aquaculture associations to increase the number of safe and effective drugs that can be used by the aquaculture industry. In February 2022, the National Science and Technology Council Subcommittee on Aquaculture (NSTC) published the Strategic Plan to Enhance Regulatory Efficiency in Aquaculture and National Strategic Plan for Aquaculture Research. CVM contributed to both plans and is currently supporting NSTC in development of the National Aquaculture Development Plan to support a robust, resilient, and environmentally sustainable domestic aquaculture sector.

Strengthening Postmarket Drug Safety

CVM is responsible for the total animal drug product lifecycle, from reviewing new animal drug applications for safety and effectiveness to monitoring the safety of approved and unapproved animal drugs marketed in the U.S. CVM also partners with FDA's Center for Drug Evaluation and Research (CDER) to respond to postmarket drug safety concerns when animals are accidentally exposed to human drugs.

In September 2022, CVM and CDER issued a drug safety communication reminding pet owners, veterinarians, and pharmacists that pets may become seriously ill or die when exposed to topical fluorouracil. This drug is used on people's skin to treat a variety of conditions, including certain types of skin cancer, and CVM received reports of dogs having serious reactions after being accidentally exposed to topical fluorouracil. All the dogs died or were euthanized due to the severity of their condition. To help increase awareness about the toxicity of fluorouracil to pets, CDER asked the manufacturers of topical fluorouracil products to add a warning to the medicine containers.

CVM has the largest animal adverse event database in the world, with adverse events reported in more than 94,000,000 food animals, and approximately 941,000 companion animals. In FY 2022, CVM had the capacity to review only 25% of the postmarket safety information it received for all approved actively marketed animal drug products; the Center lacks the capacity to respond to all but the most critical safety signals detected from adverse event reports associated with approved and unapproved animal drugs. There are more than 1,600 drugs that are FDA-approved, conditionally approved or indexed for use in animals, as well as approximately 20,000 FDA-approved human drugs that could be prescribed for animal use. At the same time, there are many different species of animals, each with various diseases and conditions for which no suitable FDA-approved or indexed drugs are available.

Animal drugs compounded from bulk drug substances are used by veterinarians in the U.S. to treat the wide diversity of animals and disease conditions. In April 2022, CVM issued final Guidance for Industry (GFI) #256, "Compounding Animal Drugs from Bulk Drug Substances," to help protect animal health by recognizing the need for access to certain compounded animal drugs. This policy balances maintaining access to compounded drugs that veterinarians need to treat diverse animal populations and protecting human and animal health from poorly compounded products, or ones that copy existing FDA-approved drugs. CVM plans to focus on education and stakeholder engagement before shifting resources toward oversight activities. Since publication of the final guidance, CVM has arranged and participated in more than forty meetings with various stakeholder groups including compounding pharmacies and associations for states, pharmacists, and veterinarians. Based on feedback from these meetings, CVM delayed implementation of inspections until April 2023. CVM will take appropriate actions, as we currently do, when compounding practices threaten human or animal health.

Supporting Antimicrobial Stewardship

CVM ensures the safety and effectiveness of animal drugs, including antimicrobials. Antimicrobial drugs have been successfully and widely used in medicine for more than 75 years to effectively fight bacterial infections in humans and animals. When bacteria develop resistance to an antimicrobial drug, that drug may be less effective in fighting infections caused by those bacteria.

In FY 2022, CVM released a progress report showing completion of 88% of the Phase I actions outlined in its five-year action plan, "Supporting Antimicrobial Stewardship in Veterinary Settings: Goals for Fiscal Years 2019 - 2023." This plan builds on past successes and applies a risk-based approach to:

- evaluating new and currently approved antimicrobial products for animals;
- collaborating with stakeholders to support stewardship of these products by end users; and
- collecting data on antimicrobial sales, use, and resistance to monitor the effectiveness of these actions to slow the development of resistance.

In December 2022, CVM published the 2021 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals. Since the significant decrease in sales volume in 2017, annual sales of medically important antimicrobials have remained at reduced levels. Compared to 2015 (peak year of sales), 2021 sales decreased 38 percent. Although sales data

provide insights regarding antimicrobial drugs entering the marketplace, it is also important to consider additional sources of information when assessing the progress of CVM's efforts to combat antimicrobial resistance, including actual use data, animal demographic information, animal health data, and data on resistance.

CVM also released the "Antimicrobial Use and Resistance in Animal Agriculture in the United States" report to provide data elements to help describe antimicrobial use and resistance in animal agriculture in the U.S. While progress is being made in animal agriculture to reduce the threat of antimicrobial resistance, there are still important knowledge and data gaps that need to be filled to inform risk assessments. Some of these gaps include the need for:

- routine surveillance of animal health issues which necessitate antimicrobial use,
- enhanced antimicrobial resistance data, including additional sources and pathogens,
- ongoing monitoring of on-farm antimicrobial use practices, and
- research on antimicrobial alternatives and other disease prevention strategies that could effectively reduce the need for antimicrobials.

To help bridge these gaps, CVM engaged the Reagan-Udall Foundation for the FDA to facilitate conversations with relevant stakeholders to assess the feasibility of creating a public-private partnership to develop an antimicrobial drug use data repository to foster antimicrobial stewardship in food-producing animals. Establishing a system for collecting representative data on antimicrobial use in animal production could benefit public and animal health by:

- improving understanding of antimicrobial drug use in veterinary settings;
- promoting antimicrobial stewardship in animal production and veterinary setting to maintain their effectiveness in both human and animal health; and
- enhancing transparency regarding antimicrobial use in food-producing animals by providing public access to appropriately aggregated/de-identified summary data.

In December 2022, CVM issued a draft update to GFI #152, *"Evaluating the Safety of Antimicrobial New Animal Drugs with Regard to their Microbiological Effects on Bacteria of Human Health Concern."* This guidance is a tool for assessing the risk of antimicrobial resistance in people, which could result from the use of a medically important antimicrobial drug in food-producing animals, and it was updated to reflect the following changes:

- updates to the guidance include revisions to the risk assessment framework,
- updated ranking criteria for determining the degree of medical importance of antimicrobial drug classes, and
- 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). CVM is improving data sharing, communication and collaboration using 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. A drug's conditions of use may be limited based on this risk estimation to 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 establishes over-arching goals, including operating within a One Health paradigm. In FY 2022, NARMS developed a novel DNA sequencing approach for profiling antimicrobial resistance in water. This approach will improve antimicrobial resistance monitoring under One Health by allowing samples from the environment to be compared to resistance found in human clinical cases and in food animals. Outcomes from this work include a better understanding of the source of antimicrobial resistance in human infections. Advances in Whole Genome Sequencing (WGS) are revolutionizing infectious disease diagnosis and surveillance by providing a complete picture of antibiotic resistance genes and other genes relevant to food safety, as well as serving as a method to compare bacteria from different sources in an outbreak.

In April 2022, NARMS released the 2019 Integrated Summary, combining antimicrobial resistance data in bacteria isolated from humans (by CDC), raw retail meats (by FDA), and animals at slaughter (by USDA) 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 this process can be time- and resource-intensive, NARMS makes the most recent data available online through the NARMS Now: Integrated Data tool.

Animal Food Safety Lifecycle

Animals generally eat a very limited and defined diet as their sole ration for their whole lifetime. CVM review of new animal food ingredients allows livestock producers to use new scientific discoveries and provide new 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, ORA and State partners also oversee the animal food industry as ingredients are combined, packaged, and sold as animal food. Improving domestic mutual reliance depends on building an integrated partnership that enables FDA and states with comparable regulatory public health systems to coordinate and leverage one another's work, data, and actions, as trusted partners to meet the public health goal of a safe human and animal food supply.

Reviewing Animal Food Ingredients

The animal food ingredient industry is rapidly evolving, and 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 that breaks down the mycotoxin fumonisin into safe substances. Fumonisin can occur in grains such as corn when the plant is subject to hot and dry weather, followed by high humidity. These conditions can lead to growth of the mold that makes fumonisin. This toxin negatively impacts animal health and growth and can be passed through into human foods. This enzyme 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 has utilized increased funding to hire more staff and improve timeliness of pre-market review of multifaceted and innovative new animal food ingredients. Additionally, CVM is reviewing its Policy and Procedures Manual (PPM) Guide 1240.3605, 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 public listening session to gain stakeholder input on potential changes resulting from this review. Substances that benefit animal production, the environment, human food safety, and or the animal's microbiome and positively impact animal agriculture are a part of the discussions as to the best way to regulate them to ensure safety, effectiveness, and provide innovative products to animal producers.

Strengthening Animal Food Oversight

Comprehensive and risk-based oversight of the animal food supply is vital to protecting the health of both humans and animals. Exposure to improperly formulated, contaminated, mislabeled, or adulterated animal foods, whether intentional or not, can cause illness or death in animals. A risk-based approach helps ensure 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 food spreading pathogens to humans.

In FY 2022, CVM combined the comprehensive inspection model that was implemented in 2021 with the risk-ranked animal food inventory to implement a risk-based inspection program. The modernized work planning model is flexible, allowing for FDA and state partners to use the risk-ranked inventory, as well as additional real-time risk information (e.g., complaints, recalls) to prioritize facility inspections throughout year. Each facility in the workplan will receive a comprehensive animal food inspection, ensuring that all of the types of regulated activities the facility performs are reviewed during the inspection. This approach helps ensure a holistic, risk-based, and prevention-oriented approach to inspections and will better utilize resources of both the Center, ORA, and state inspection partners to ensure greater inspectional oversight of the animal food industry. The comprehensive approach to inspections has allowed us to help facilities correct deficiencies that were found during inspections that have or could lead to adulterated animal food.

In July 2022, CVM finalized GFI #245, *"Hazard Analysis and Risk-Based Preventive Controls for Food for Animals,"* to provide detailed information to help animal food facilities

- anticipate possible food safety hazards,
- identify risk-based preventive controls to prevent or minimize those hazards, and
- create and implement a plan to help keep unsafe animal food from entering the marketplace.

Strengthening Domestic Mutual Reliance

CVM and ORA supported the Preventive Controls for Animal Food (PCAF) rule implementation with 13 states enrolled in the Animal Food Regulatory Program Standards (AFRPS) cooperative agreement in FY 2020. The FY 2022 budget authority is being leveraged to provide additional cooperative agreement awards to state regulatory programs and supporting animal food regulatory associations. Expansion supplements were awarded to 2 states under the AFRPS cooperative agreements for grantees to conduct compliance and enforcement work resulting from

violative animal food samples analyzed under the Laboratory Flexible Funding model cooperative agreement.

Under the New Era of Smarter Food Safety, a partnership agreement was signed with Minnesota to support mutual reliance efforts. This is the first partnership agreement that includes both human and animal food. The partnership agreement's key areas will work to leverage each other's resources to support the vision of an integrated food safety system through:

- data information and sharing
- official establishment inventory reconciliation and maintenance; and
- identifying, establishing and monitoring key mutual reliance metrics.

CVM also co-led the Food Safety Summit on E-Commerce: Ensuring the Safety of Foods Ordered Online and Delivered Directly to Consumers to seek feedback on food safety and business trends with direct-to-consumer sales and delivery of pet food using e-commerce. The feedback obtained during the summit will be used to inform regulatory program decisions in this emerging area of pet food business.

Preparedness and Response

CVM recognizes the principle of One Health, that the health of humans, animals, and the environment are intertwined. Expansion of human and animal populations, changes in climate and land use, political conflict, and increased international travel and trade provide greater opportunities for infectious disease transmission. An approach that tries to solve complex public health issues without a complete and combined understanding of the human, veterinary, and environmental aspects can lead to missed opportunities for earlier detection and mitigation.

Approximately 75 percent of recently emerging infectious diseases affecting humans, including HIV, Ebola, and influenza, are zoonotic (i.e., spread from animals to humans).[69] It is also clear that humans are transmitting diseases to animals in what is often referred to as "reverse zoonoses." CVM is working with the U.S. Department of Agriculture (USDA), Center for Disease Control and Prevention (CDC) and other agencies to monitor the ongoing outbreak of Monkeypox (MPox) in people. Consumer information has been released about pets in households of infected people with Mpox and CVM's Vet-LIRN has coordinated with USDA National Animal Health Laboratory Network on animal diagnostic testing.

CVM's Vet-LIRN also led three inter-laboratory comparison exercises among 47 veterinary diagnostic laboratories to ensure that their tests for the COVID-19 virus, SARS-CoV-2 are reliable for use in animals. Exercises included the original sequence, along with alpha, beta, delta, and omicron variants 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 human tests for SARS-CoV-2 and 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.

[69] World Organization for Animal Health (the OIE) (2018). – One Health "at a glance". Available at: http://www.oie.int/en/for-the-media/onehealth/ (accessed 28 Sep 2018).

FDA's ability to monitor the animal drug supply chain is being strengthened by the development of the Animal Drug and Manufacturing System (ADMS) funded by COVID-19 supplemental resources. The new tool will enable animal drug manufacturers to provide more complete facility information and enable CVM to rapidly access information on animal drug products, active pharmaceutical ingredients, and the status of manufacturing sites to identify and address critical facilities and animal drugs impacted by emerging diseases or natural disasters.

While the system is being created, CVM continues to monitor the animal drug supply chain and voluntarily solicit information from animal drug sponsors to ascertain, as early as possible, any shortage or potential shortage. In June 2022, CVM averted a shortage of Vetmedin, the only FDA-approved drug to treat congestive heart failure in dogs. The lifesaving cardiac drug remained available to U.S. consumers because FDA collaborated with the firm and exercised enforcement discretion for the temporary importation of the firm's foreign-authorized Vetmedin. Early notification is critical in order to help the Center in its efforts to prevent or mitigate shortages of these products.

PERFORMANCE

The Animal Drugs and Foods Program's performance measures focus on premarket animal drug application review, high risk inspections including BSE, 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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
243201: Complete review and action on Non-administrative original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year. (Output)	FY 2021[70]: 100% w/in 180 days Target: 90% w/in 180 days (Target Exceeded)	90% w/in 180 days	90% w/in 180 days	Maintain
243202: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year. (Output)	FY 2021[71]: 100% w/in 240 days Target: 90% w/in 240 days (Target Exceeded)	90% w/in 240 days	90% w/in 240 days	Maintain
244204: Complete review and action on warning letters to better safeguard U.S. consumers by alerting firms to identified deviations in order to become compliant. (Output)	FY 2022: 67% w/in 25 working days Target: 50% w/in 25 working days (Target Exceeded)	50% w/in 25 working days	50% w/in 25 working days	Maintain

[70] Represents FDA's final performance for FY 2021 cohort submissions.

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
244302: Respond to consumer complaints by initiating in-depth Vet-LIRN investigations. within 30 days of receipt. (Output)	FY 2022: 100% Target: 90% w/in 30 working days (Target Exceeded)	90% w/in 30 working days	90% w/in 30 working days	Maintain
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2022: 97.7% 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 2022: 93.4% 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 2022: 72.7% 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 2022: 56.8% Target: 55% (Target Exceeded)	55%	55%	Maintain

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

New Animal Drug Application Review

In FY 2021, CVM completed review and action on 100 percent of non-administrative original NADAs and reactivations within the timeframes specified. CVM also completed review and action on 100 percent of non-administrative original ANADAs and reactivations within the timeframes specified.

Warning Letters

In FY 2022, CVM exceeded the performance target for completing Center recommendations for 50% 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 safety issues. The Network's 47 state and university veterinary diagnostic laboratories contributed to the initiation of 64 cases investigations in FY 2022 where there was compelling indication of harm caused by a regulated product and where animal diagnosis samples were available for testing. 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.

PROGRAM ACTIVITY DATA

Animal Drugs & Foods Program Activity Data (PAD)

CVM Workload and Outputs	FY 2022 Estimate	FY 2023 Estimate	FY 2024 Estimate
New Animal Drug Applications (NADAs) [1]			
Received	12	13	13
Completed	12	12	12
Approved	10	11	11
Pending [2]	13	15	16
New Animal Drug Application Supplements [1, 3]			
Received	528	515	515
Completed	524	500	530
Approved	452	420	430
Pending [2]	201	197	182
Abbreviated New Animal Drug Applications (ANADAs) [1]			
Received	20	22	22
Completed	30	22	20
Approved	28	18	18
Pending [2]	2	2	4
Abbreviated New Animal Drug Application Supplements [1, 3]			
Received	457	425	425
Completed	378	425	425
Approved	361	375	375
Pending [2]	247	247	247
Investigational New Animal Drug (INAD) Files [4]			
Received	2,817	2,900	2,900
Completed	2,931	2,900	2,900
Pending [2]	317	266	266
Generic Investigational New Animal Drug (JINAD) Files [4]			
Received	976	1,000	1,000
Completed	1,021	1,000	1,000
Pending [2]	111	91	91
Food (Animal) Additive Petitions Completed	66	55	60
Investigational Food Additive Petitions Completed	63	70	70
Adverse Drug Event (ADE) [5]			
ADE Reports Received	84,397	90,000	90,000
Post-Approval ADE Data Reviews	283	300	300

[1] Includes original applications and reactivations. If the application is not approvable, the sponsor may submit additional information until FDA is able to approve the application.

[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. Supplemental applications can be significant (such as a new species or indication), or routine (such as product manufacturing changes). The estimates do not include invited labeling change supplement applications because it is not possible to accurately project sponsor or CVM requests for this type of application.

[4] An INAD or JINAD file is established at the request of the sponsor to archive all sponsor submissions for a phased drug review including requests for interstate shipment of an unapproved drug for study, protocols, technical sections, data sets, meeting requests, memos of conference, and other information. Excluded from this count are Agency initiated actions (Q submissions) and amendments to INAD submissions.

[5] This measure tracks the number of "Post-approval ADE data reviews" completed each fiscal year. A Post-approval ADE Data Review is a comprehensive report by product of multiple ADE reports (in some cases this could be hundreds or thousands of individual reports).

Figure 40 - CVM Workload and Outputs

Field Animal Drugs & Foods Program Activity Data (PAD)									
Field Animal Drugs and Foods Program Workload and Outputs	**FY 2022 Estimate**			**FY 2023 Estimate**			**FY 2024 Estimate**		
	Total	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS	***855***	***70***	***785***	***1,225***	***132***	***1,094***	***1,225***	***132***	***1,094***
Pre-Approval /BIMO Inspections	24	24	0	36	36	0	36	36	0
Drug Process and New ADF Program Inspections	44	44	0	94	94	0	94	94	0
BSE Inspections	227	0	227	476	0	476	476	0	476
Feed Contaminant Inspections	0	0	0	2	0	2	2	0	2
Illegal Residue Program Inspections	108	0	108	254	0	254	254	0	254
Feed Manufacturing Program Inspections	181	0	181	190	0	190	190	0	190
Domestic Laboratory Samples Analyzed	437	0	437	976	5	971	976	5	971
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS1	***21***	***12***	***9***	***62***	***45***	***17***	***62***	***45***	***17***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	9	8	0	15	15	0	15	15	0
Foreign Drug Processing and New ADF Program Inspections	6	6	0	32	32	0	32	32	0
Foreign Feed Inspections	0	0	0	2	0	2	2	0	2
BSE Inspections	1	0	1	2	0	2	2	0	2
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS	***876***	***82***	***794***	***1,287***	***176***	***1,111***	***1,287***	***176***	***1,111***
IMPORTS									
Import Field Exams/Tests	2,870	791	2,079	3,078	827	2,252	3,078	827	2,252
Import Laboratory Samples Analyzed	536	0	536	799	0	798	799	0	798
Import Physical Exam Subtotal	**3,406**	**791**	**2,615**	**3,877**	**827**	**3,050**	**3,877**	**827**	**3,050**
Import Line Decisions	572,292	81,003	491,289	578,015	81,813	496,202	583,795	82,631	501,164
Percent of Import Lines Physically Examined	0.60%	0.98%	0.53%	0.67%	1.01%	0.61%	0.66%	1.00%	0.61%
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***987***	***0***	***987***	***2,055***	***0***	***2,055***	***2,055***	***0***	***2,055***
State Contract Inspections: BSE	433	0	435	1,389	0	1,389	1,389	0	1,389
State Contract Inspections: Feed Manufacturers	266	0	266	447	0	447	447	0	447
State Contract Inspections: Illegal Tissue Residue	$2,583,086	0	$2,583,086	$2,608,917	0	$2,608,917	$2,635,006	0	$2,635,006
	1,863	82	1,781	3,342	176	3,166	3,342	176	3,166
State Contract Animal Feeds Funding	$2,716,170	0	$2,716,170	$2,743,331	0	$2,743,331	$2,770,765	0	$2,770,765
State Contract Tissue Residue Funding	$0	0	$0	$0	0	$0	$0	0	$0
Total State Funding	**$2,716,170**	**$0**	**$2,716,170**	**$2,743,331**	**$0**	**$2,743,331**	**$2,770,765**	**$0**	**$2,770,765**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,858***	***182***	***2,676***	***5,032***	***283***	***4,749***	***5,032***	***283***	***4,749***

[1] The FY 2021 actual unique count of foreign inspections includes 4 OGPS inspections (4 for China).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

[3] The State cooperative agreement BSE inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number along with the funding for these inspections are expected to decrease in the future until there are no planned State Cooperative Agreement BSE inspections.

[4] Tissue residue funding has ended in FY18 and state contract illegal tissue residue inspections are no longer being conducted.

[5] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 41 - Field Animal Drugs and Foods Program Workload and Outputs

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 and 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).

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Devices and Radiological Health	**587,305**	**642,791**	**647,467**	**745,949**	**791,857**	**45,908**
Budget Authority	***395,142***	***408,108***	***419,457***	***449,297***	***477,990***	***28,693***
User Fees	***192,163***	***234,683***	***228,010***	***296,652***	***313,867***	***17,215***
Center	488,115	542,939	545,670	637,459	679,046	41,587
Budget Authority	310,156	323,103	331,904	356,062	380,952	24,890
User Fees	177,959	219,836	213,766	281,397	298,094	16,697
Field	99,190	99,852	101,797	108,490	112,811	4,321
Budget Authority	84,986	85,005	87,553	93,235	97,038	3,803
User Fees	14,204	14,847	14,244	15,255	15,773	518
FTE	**2,172**	**2,437**	**2,356**	**2,516**	**2,574**	**58**

Figure 42 - Devices Funding History Table

The FY 2024 President's Budget for the Devices Program is $791,857,000 of which $477,990,000 is budget authority and $313,867,000 is user fees. The budget authority increases by $28,693,000 compared to the FY 2023 Enacted Budget. User Fees increases by $17,215,000. The Center for Devices and Radiological Health (CDRH) amount in the request is $679,046,000. The Office of Regulatory Affairs amount is $112,811,000.

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 has to 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 2024 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 U.S. first, and FDA continues to see more first in the world approvals here in the U.S. 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 2024 funding 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 2024 President's Budget: Devices *Budget Authority - Dollars in Thousands*			
	Center	**Field**	**Total**
FY 2023 Enacted	**356,062**	**93,235**	**449,297**
FY 2024 Budget Authority Changes	**24,890**	**3,803**	**28,693**
Advancing Medical Product Safety	**17,058**	**-**	**17,058**
Device Shortages and Supply Chain	11,600	-	11,600
Postmarket Safety Collaborative	3,000	-	3,000
Advancing the Goal of Ending the Opioid Crisis	1,150	-	1,150
Medical Product Safety Data Modernization	985	-	985
ACT for ALS	323	-	323
Investing in Core Operations - Crosscutting	**12,229**	**5,172**	**17,401**
Enterprise Data and IT Modernization	1,083	259	1,342
Public Health Employee Pay Costs	10,141	4,647	14,788
OC Regulatory and Mission Support	1,005	266	1,271
Other Adjustments	**(4,397)**	**(1,369)**	**(5,766)**
ORA Transfer to HQ/OGPS	-	(1,936)	(1,936)
FDARA Sec. 905 BA Shift	(5,320)	(63)	(5,383)
Comparability Adjustment	923	630	1,553
FY 2024 Budget Net Total: Devices	**380,952**	**97,038**	**477,990**

Figure 43 - Devices Budget Authority

Medical Product Safety: $17.1 million / 14 FTE

Device Shortages and Supply Chain: +$11.6 million / 10 FTE

Center: +$11.6 million / 10 FTE

The FY 2024 President's Budget request provides $11.6 million for Shortages and Supply Chain for the Center of Devices and Radiological Health. The budget builds on FY 2023 funding and will be used to continue building capabilities for FDA's Resilient Supply Chain and Shortages Program for medical devices and recruiting data science, supply chain and medical device expertise. This program will work proactively with medical device stakeholders to enhance resiliency in the supply chain of critical medical devices and prevent shortages of critical devices that most often impact vulnerable populations.

FDA consistently works to prevent shortages of medical devices; however, it is challenging for the Devices Program to support an optimally resilient supply chain, as the FDA does not have the same authorities for device shortages it has for drugs and has overall limited statutory authority to get the information it needs to intervene before shortages and other disruptions occur. Despite limits in its authority, FDA is proactive, reaching out to companies to get the information we need, though it is always a manual, time-consuming and challenging process because medical device companies are not required to notify FDA about potential supply chain disruption or to respond to requests for information from FDA except for under limited circumstances.

FDA is also working with hospitals, physician societies, patient organizations and other groups to understand the impacts of medical device shortages and take appropriate action. In order to mitigate the impact of medical device shortages, FDA is also analyzing other potential sources of supply chain disruptions to include but not limited to: geopolitical, weather, and recalls. FDA aims to expand our shortage capabilities to be more proactive, preventing future disruptions and shortages.

Advancing the Goal of Ending the Opioid Crisis: +$1.2 million / 3 FTE

Center: +$1.2 million / 3 FTE

The FY 2024 President's Budget requests includes an increase of $23.0 million for Advancing the Goal of Ending the Opioid Crisis, including $1.2 million for CDRH.

The opioid epidemic has only worsened during the COVID-19 pandemic and the nation needs to use every tool at its disposal to address opioid use disorder (OUD). Medical devices play a critical role in FDA's all-hands on deck approach to confronting the opioid crisis. In particular, digital health technologies are being developed to identify those at risk for or to diagnose those with OUD as well as to treat or manage the disorder. CDRH is requesting $1.2 million to advance the development, evaluation, and market authorization of digital health medical devices that help address OUD including hiring subject matter experts including data scientists and clinicians to build and increase capacity and coordinate the effort.

Funds will be used for hiring staff for actions that include establishing a streamlined framework for FDA market authorization based on evolving science and technology, enabling infrastructure to enhance capabilities to leverage real world data to support evaluation of OUD digital health technology, and incentivizing the development of new safe, effective, high-quality digital risk assessments, diagnostics, and therapeutics and novel outcome assessments using DHTs, such as through a design-a-thon and other crowdsourcing measures. The additional funds will build on the ongoing patient preference study to understand what benefits and risks people living with OUD are willing to accept using digital health technologies which can help inform clinical trial design and the framework for marketing authorization.

FDA recognizes the risks of 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 opioids and other controlled substances and ameliorate the overdose crisis is among FDA's highest priorities. FDA is engaging in many activities aimed at furthering these goals.

In alignment with HHS' Overdose Prevention Strategy, FDA has identified four specific Overdose Prevention Priorities to provide a framework and focus for FDA's actions to address the crisis.

Medical Product Safety Data Modernization: +$985,000

Center: +$985,000

The FY 2024 President's Budget request includes an FDA increase of $3.0 million for Data Modernization and Enhanced Technologies – Medical Product Safety, to include $985,000 for CDRH to support the program's Digital Transformation initiative.

Timely patient and consumer access to new, safe, innovative devices and continued safeguards depend on FDA having modernized IT systems. Having an Enterprise Search system is essential for improving the health and quality of life of patients while assuring critical safeguards. Enhancing Enterprise Search capacity functions would make it easier for reviewers to do their work more efficiently, which would improve CDRH's ability to more quickly identify and address safety signals, and spur the development of devices that are more innovative, safer, and more effective.

Through the Devices Program's Digital Transformation initiative, the Program will be able to use this funding to continue to make advances in the Enterprise Search capabilities at CDRH. The Program will enhance the Enterprise search tool to improve external and internal search capabilities, and proactively find, access, and display related submission information. This investment will make the review of device applications and postmarket surveillance more efficient, enable faster decision making, and provide timelier patient access to innovative, safe, effective, high-quality devices.

ACT for ALS: +$323,000 / 1 FTE

Center: +$323,000 / 1 FTE

The FY 2024 President's Budget request includes an FDA increase of $2.5 million, including $323,000 for CDRH to implement ACT for ALS, including implementation of the ACT for ALS Action Plan, operation of the Public Private Partnership, and grant awards under FDA Rare Neurodegenerative Disease Grant Program.

As part of the Action Plan, FDA will bolster scientific advancement and promote innovation for rare neurodegenerative diseases by establishing a task force and a public-private partnership for rare neurodegenerative diseases, developing disease-specific science strategies and leveraging FDA's regulatory science efforts. The regulatory efforts include facilitating patient participation in clinical trials by diverse populations (including utilizing digital health technologies and decentralized clinical trials designs) and improving the characterization of ALS pathogenesis and natural history including quantifying disease progression as well developing predictive and prognostic biomarkers. Key to the success of these efforts includes patient engagement, public workshops, research projects, and coordination and collaboration across FDA centers, offices, and the National Institute of Health.

Activities under the ACT for ALS were recently mandated by Congress, and the FY 2024 Budget will provide FDA with resources to begin implementation, including the ability to issue grants and contracts and hire FTE. With a dedicated source of funding, FDA will be able to implement activities outlined in the ACT for ALS Action Plan such as fostering the creation of innovative diagnostic tools, clinical outcome assessments, patient preference information surveys, and digital health technologies, which have the potential to impact the development, evaluation, and implementation of future therapeutics. This initiative will also provide funds necessary to hire staff to facilitate research activities associated with advancing the activities necessary for the development and evaluation of impactful medical devices, including digital health technologies.

Postmarket Safety Collaborative: +$3.0 million

Center: +$3.0 million

The FY 2024 President's Budget requests an increase of $10.1 million for Strengthening FDA Postmarket Safety Collaborative, including $3.0 million for CDRH, to enhance safety surveillance and oversight programs within CDER, CDRH, and CVM, to develop more efficient and effective detection, evaluation, prevention, and mitigation of adverse events. Protecting the health of humans and animals requires FDA to continuously enhance its safety surveillance and oversight programs, consistent with advances in the science of drug and device safety. New scientific approaches and new and improved tools are available and needed for the efficient and effective detection, evaluation, prevention, and mitigation of adverse events.

CDRH will use the $3.0 million included in the FY 2024 budget to further develop an active surveillance system for medical devices, advancing FDA's use of real-world evidence in postmarket safety by enhancing data infrastructure which will support safety signal identification and refinement using a federated network of collaborators. This work will integrate critical medical device safety information into timely FDA communications that can guide decision making for patients and caregivers while informing CDRH's total product life cycle evaluation of medical devices. In addition to applied COVID-19 use cases, some COVID-19 supplemental funding has been used for development of an active surveillance system. Further development of the system to bring more diverse data sources and build capacity beyond COVID-specific medical device will not occur in the absence of receiving this funding. The system is intended to be a key component for FDA postmarket safety monitoring moving forward with active surveillance activities being conducted for the foreseeable future.

This funding would be complementary to the $23 million in recurring postmarket safety funds that CDRH has been receiving since FY 2019. The FY 2024 Budget will allow FDA to build off these initial investments in data infrastructure and analytics by leveraging cooperative agreement(s) and contract(s), as needed, to bring a diverse set of data collaborators onboard, and conduct active surveillance activities within the system. The $23 million in recurring postmarket funds would continue to support two other important safety programs – postmarket safety studies that leverage extant real-world data that FDA does not routinely have access to and the development and application of artificial intelligence/machine learning (AI/ML) to enhance device safety through improved detection and refinement of safety signals. The new funding request to develop an active surveillance system would complement these other important safety programs by providing CDRH with the infrastructure needed for near-real-time evidence evaluation of multiple sources of complementary but distinct data related to device performance, use and safety.

Crosscutting: $17.4 million / 6 FTE

Public Health Employee Pay Costs: +$14.8 million

Center: +$10.1 million

Field: +$4.7 million

The FY 2024 Budget provides $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and

Military FTE funded through budget authority. Within the Devices program, $14.8 million is provided for pay costs.

OC Regulatory and Mission Support: +$1.3 million / 5 FTE

Center: +$1.0 million/ 3 FTE

Field: +$266,000 / 2 FTE

The FY 2024 Budget includes $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within Devices program, $1.3 million is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$1.3 million / 1 FTE

Center: +$1.1 million/ 1 FTE

Field: +$259,000

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $1.3 million for the Devices and Radiological Health program, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

USER FEES

Current Law User Fees: +$16.8 million

Center: +$16.6 million

Field: +$279,000

The Devices Program request includes an increase of $16.8 million for user fees which 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

The Devices Program oversees development of new devices that make less-invasive treatments 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]

There are 235,000 different types of medical devices on the U.S. market, manufactured at nearly 30,000 facilities worldwide. FDA's Center for Devices and Radiological Health (CDRH) handles over 20,000 submissions each year – including meeting requests – as well as reviewing medical devices (adverse event/malfunction) reports. The Center approves or clears, on average, 12 new or modified devices every business day, authorizing and clearing thousands of products

[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.

for entry into the market, and 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 medical devices that patients and their 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 opioid products, laser surgical devices, and artificial intelligence/machine learning technologies that help with earlier detection of diseases and conditions, among others. Medical devices also include in vitro diagnostic products, such as next generation sequencing tests, tests for COVID-19 and other emergent diseases, 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 medical devices according to the degree of risk presented, so it can focus its resources on those products that pose the most risks to patients.

The Devices Program works with federal partners, hospitals, and 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 44 - 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 high-quality, safe and effective medical devices to meet patient needs, and consistently works to protect patients and enhance safety. We are equally committed to advancing safe and effective products 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:

- One way that we are measuring the success of our efforts is through tracking the number of innovative medical technologies being brought to the U.S. first so that patients have access to the safest and most innovative devices available. The Center's efforts have resulted in 103 novel devices receiving marketing authorization in calendar year 2021, despite the unprecedented demands of our pandemic response.
- 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 number of approved early feasibility studies in the U.S. where devices are evaluated early in development has more than doubled – from 21 in FY 2014 to 39 in FY 2021.
- Conducted timely review of more than 3 million medical device adverse event reports received in FY 2022 and completed other pivotal work activities such as addressing supply chain shortages and counterfeit products related to COVID-19.

The Devices Program's success in providing patients with new options for effective health care, on robust non-clinical and clinical science. In some cases, we are receiving clinical evidence more quickly and more efficiently and answering post-market questions we would not have been able to easily address in the past, due in part to our efforts to strengthen the clinical trial enterprise and leverage real world data.

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, more and more 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 it was established in late 2016 by the 21st Century Cures Act. This program is intended to help patients have more timely access to devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

In FY 2022, FDA granted over 160 Breakthrough Device designations, bringing the total to more than 700 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. For example, in FY 2022, a De Novo request was granted for a Breakthrough prescription-use immersive virtual reality system that uses cognitive behavioral therapy and other behavioral methods to help with pain reduction in patients 18 years of age and older with diagnosed chronic lower back pain. This authorization is notable because it offers a treatment option for pain reduction that does not include opioid pain medications when used alongside other treatment methods for chronic lower back pain.

Additionally, in FY 2022, FDA approved a PMA for a Breakthrough Device designed to repair or replace damaged or diseased vessels of the aortic arch and descending aorta in cases of aneurysm and/or dissection, as well as granted a De Novo request for a Breakthrough Device that helps improve swallowing in patients with severe dysphagia (difficulty swallowing) post stroke.

Cybersecurity

Patients, industry, other federal agencies, and all segments of the ecosystem – including healthcare delivery organizations and researchers - depend on FDA to help assess the scope of threat and harm to patients, coordinate mitigations, and support our entire health care system to help prevent harm from coming to patients. The Devices Program's goal is to encourage a coordinated approach of vigilance, responsiveness, resilience, and recovery with respect to cybersecurity that fits FDA's culture of continuous quality improvement. This means taking a total product lifecycle approach, starting at the product design phase when FDA encourages manufacturers to build 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 has published guidances 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:

- 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. An updated draft was published in April 2022, and the Devices Program is currently resolving comments that we received.

- Updating the Medical Device Cybersecurity Regional Incident Preparedness and Response Playbook via a contractor to account for lessons learned since its original publication in 2019.
- Working with HHS, the Administration, and Congress regarding proposals for additional, explicit authority for FDA to regulate medical device cybersecurity.
- Collaborating across FDA centers such as CFSAN and CDER to share information on cybersecurity efforts, as well as to address shared cybersecurity topics, such as cyber incident reporting.
- 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.
- Aiding in the amplification and convergence of international cybersecurity best practices as co-chair of the International Medical Device Regulators Forum.
- Collaborating with industry on cybersecurity challenges such as legacy medical devices and vulnerability communications via the Healthcare and Public Health Sector Coordinating Council (HSCC) public-private partnership. The Vulnerability Communications task group—co-lead by Devices Program staff—published its first round of materials on patient communication best practices in the spring, and has begun work on a second round related to business-to-business best practices.

FDA participates in the HHS Cybersecurity Working Group and works collaboratively with the CISA of the Department of Homeland Security (DHS) as well as the Federal Bureau of Investigations (FBI). FDA also works with the Federal Communications Commission (FCC) in the Cybersecurity Forum for Independent and Executive Branch Regulators. Further, FDA is engaging with the National Institutes of Standards and Technology (NIST) and other federal agencies on the President's Executive Order (EO) on Improving the Cybersecurity of the Federal Government (EO 14028).

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. The DHCoE released the final guidance on Clinical Decision Support Software, completing the FDA's interpretation of the 21st Century Cures Act software provisions. When the guidance was released, the DHCoE also released the Digital Health Policy Navigator, which is a tool to help product developers and other stakeholders in determining whether their product's software functions are potentially the focus of the FDA's oversight. The DHCoE also collaborated across the agency to release draft guidance Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders.

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 a Good Machine Learning Practice for Medical Device Development: Guiding Principles document with Health Canada and the UK's Medicines and Healthcare products Regulatory Agency (MHRA) and a Machine Learning-enabled Medical Devices: Key Terms and Definitions document with the International Medical Device Regulators Forum (IMDRF) to promote harmonization of key terms of principles. In addition, the DHCoE issued and updated a list of AI/ML-enabled medical devices, which includes over 500 authorized devices. This list serves as a resource to the public about these devices and the FDA's work in this area.

Over the past five years, the DHCoE has developed the Software Precertification (Pre-Cert) Pilot Program to foster innovative technologies and advance FDA's mission to protect and promote public health. In September 2022, the DHCoE completed the Pre-Cert Pilot Program with the issuance of the Report: The Software Precertification (Pre-Cert) Pilot Program: Tailored Total Product Lifecycle Approaches and Key Findings.

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, software, and patient-generated health data. 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. In addition, the DHCoE coordinated the Patient Engagement Advisory Committee to discuss and make recommendations on Augmented Reality (AR) and Virtual Reality (VR) Medical Devices, including vulnerable patients like pediatrics.

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. Since issuing the guidance on patient preference information in 2016, industry is increasingly including this information in medical device submissions, growing from initially none to 25 studies that are completed or in the pipeline. In addition, patient-reported outcomes are being collected consistently in more than 50 percent of medical device submissions with clinical studies. To facilitate greater inclusion of the patient perspective in medical device submissions, FDA issued final guidance on least burdensome, best practices for developing, selecting, and modifying patient-reported outcome instruments.

The Devices Program also established the first advisory committee comprised solely of patient and family caregiver representatives and is working hand-in-hand with patients to incorporate

their values and perspectives into all aspects of the medical device total product life cycle -the Patient Engagement Advisory Committee (PEAC). FDA integrated PEAC recommendations into a final guidance, Patient Engagement in the Design and Conduct of Medical Device Clinical Studies, on the ways patients can engage as advisors in the design of clinical studies.

The PEAC has provided insightful recommendations on matters including patient involvement as advisors in medical device clinical investigations, patient-generated health data as evidence to monitor and promote medical device safety, communicating cybersecurity vulnerabilities and medical device recalls, as well as transparency around artificial intelligence/machine learning-enabled and virtual and augmented reality devices. The PEAC recommendations have been used to inform FDA actions such as issuing best practices for communicating cybersecurity vulnerabilities to patients as well as posting a video to help inform patients of how to protect their medical devices from cybersecurity threats. Based on the advice from PEAC members, FDA held public workshops to further discuss elements of generating robust patient-generated health data and fostering greater transparency in artificial intelligence/machine learning-enabled medical devices.

Coronavirus (COVID-19)

It is hard to overstate the impact the global pandemic has had on the Devices Program and the entire FDA, as it did for so many individuals, organizations, and communities around the world. Responding to this public health emergency (PHE) became central to our work and pushed us into a continuous all-hands-on-deck status, working oftentimes literally around the clock to facilitate the development and availability of pandemic-related devices as quickly and safely as possible. FDA's work to support access to devices for the COVID-19 response began in January 2020 – before the PHE was declared in the U.S. and two months before the pandemic was declared worldwide – due to the immediate need for COVID-19 tests and testing supplies, collection kits, personal protective equipment (PPE), ventilators, and other devices.

The need for medical devices to respond to the COVID-19 pandemic has far exceeded what we experienced in any prior Public Health Emergency (PHE). The first EUAs issued for the COVID-19 PHE were for medical devices, and the volume of EUA requests quickly surpassed (by two orders of magnitude) that of any prior PHE or other situation. Further, the emergency use requests included submissions for devices that CDRH had never received EUA requests for during prior PHEs. This included ventilators and novel devices such as continuous renal replacement therapy devices. Since the start of the pandemic, FDA has issued EUAs or granted full marketing authorization to more than 2,600 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 healthcare 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.

From early in the pandemic, the Devices Program has actively reached out to and engaged other government agencies, medical device developers and international regulatory agencies, among other stakeholders. The Devices Program continues to hold virtual town halls with industry to address COVID19 test development and validation, as well as additional webinars and town halls addressing other policies and questions including PPE, 3D printed swabs and manufacturing disruptions during the public health emergency. The Devices Program's staff have also interacted frequently with test developers and manufacturers through the Pre-Emergency Use

Authorization (PEUA) process, including rolling reviews of information that helped to further expedite emergency use authorization (EUA) of critical medical devices for patients and health care professionals on the front lines.

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 23 over-the-counter (OTC) at-home tests, resulting in hundreds of millions of additional OTC tests available monthly to American consumers. The Devices Program also took several additional steps, including:

- Facilitating OTC COVID-19 test availability by issuing updated templates for EUA requests to streamline authorization of OTC tests;
- Partnering with the National Institutes of Health (NIH) on the Independent Test Assessment Program (ITAP) to support FDA's evaluation of OTC COVID-19 tests that have the potential for manufacturing at significant scale, where we have consistently seen shorter review times for such EUA requests; and
- Triaging our review efforts to focus on tests that ensure the biggest public health impact.

We also saw innovators across the device ecosystem mount a remarkable response – medical device manufacturers large and small turning their production lines to different types of devices, and non-traditional manufacturers who came forward to manufacture devices for the first time – all to meet the needs of an unforgiving pandemic. Our team worked closely with them, night and day, to review EUA and Pre-EUA submissions.

As of November 14, 2022, 437 tests and sample collection devices are authorized by the FDA under emergency use authorizations (EUAs). Among these are 26 EUAs for diagnostic tests that can be run at home (five molecular and 21 antigen tests), 23 of which do not require a prescription. We have also authorized 43 tests for serial screening programs (35 antigen and eight molecular). The volume and variety of available tests is a testament to FDA's support of innovative test design and our commitment to public health. FDA recognizes that medical devices, particularly tests, will continue to play an important role in the next phase of the pandemic response and in future responses. The Agency is continuing to monitor its policies, the marketplace, and national needs, and will continue to adapt as the circumstances of the evolving pandemic warrant.

Resilient Supply Chain Program

CDRH is working within its resources and 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 PHE, CDRH has received over 450 shortage signals encompassing thousands of medical devices. CDRH subsequently implemented or informed mitigations for approximately 350 of these 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 2022, CDRH made significant strides towards developing the foundation, processes, and procedures for this new Resilient Supply Chain Program (RSCP). The resources, hiring strategy and IT/data infrastructure for the program was established. In addition, the RSCP held a 3-day

public workshop to discuss resiliency in medical device supply chains and to gather stakeholder feedback on future opportunities for working collectively to identify supply chain vulnerabilities and risks and to proactively work to prevent disruptions while also developing innovative solutions to support greater resiliency. In addition, the workshop served as a platform for gathering feedback on development and value-add of this new program to our broad group of medical device stakeholders.

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 is currently leading an intergovernmental effort to Develop a Critical Medical Device List. This work is being led by FDA's CDRH and facilitated through the Health Care and Public Health Sector Critical Infrastructure Partnership Advisory Council (CIPAC). Work performed as a part of this effort will help inform: 1) investments in advanced manufacturing capabilities, processes and technologies; 2) industrial based expansion; and 3) national stockpiling. In addition, this work will support building greater resiliency in the medical device supply chain.

Case for Quality

The Devices Program has been advancing manufacturing and product quality through its Voluntary Improvement Program (VIP) Pilot. The goal of the program and pilot is to improve the safety, quality, and access of medical devices for patients by driving quality and continuous improvement within the device industry.

This focus and integration have 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.

The Devices Program has received more than 680 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. 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. One of the participants enrolled in the program has been voted best place to work in their state 3 years in a row, increasing the company's domestic manufacturing capacity. On May 5, 2022, FDA published draft 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. In response to the COVID-19 pandemic and at the request of participants who wanted to sustain the improvements, the VIP program was able to quickly adjust, develop, and incorporate virtual assessments. VIP participant sites in their 3rd year who focused on supplier management practices reported minimal to no disruption in supply during the COVID-19 pandemic due to improvements and investments implemented in collaboration with their suppliers.

Advanced Manufacturing Clearinghouse

The Devices Program has developed an advanced manufacturing clearinghouse, 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, strategies for successful implementation, and publish assessments of the technology to industry and government to promote and facilitate adoption of more effective and efficient means of manufacturing, which, over time, would enable the adoption of advanced methods and technologies in U.S. manufacturing to increase production capacity, improve quality, and reduce costs.

A collaborative evaluation project with an industry partner implementing digital technology in manufacturing showed an 85 percent reduction in quality control processing time with a 40 percent decrease in production defects and non-conformances, improving yield and product availability. The Devices Program has awarded a contract to the Medical Device Innovation Consortium (MDIC) to support development of the advanced manufacturing clearinghouse and fund an initial set of advanced manufacturing technology implementation proposals which include 1) a deep learning artificial intelligence model applied in manufacturing, 2) implementing a digitally connected enhanced lifecycle management platform, 3) establishing an intelligent risk-management control process, and 4) incorporating critical control point data integration through the production supply chain to improve supply chain oversight and responsiveness.

On September 13, 2022, the Devices Program published draft guidance, Computer Software Assurance for Production and Quality System Software, to support and accelerate the adoption of advanced manufacturing technology in the medical device industry. Results shared by early adopters of the risk-based policy outlined in the draft guidance have demonstrated 40–60% reduction in time to implement new technology, significant increases in technology implementation, and savings ranging from $6-$12 million dollars with 90-95% reduction in technology implementation errors.

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. As of July 2022, there were 8,718 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 FY2022. In the current inspection cycle, over 86 percent of mammography facilities had no serious violations and less than one percent of facilities were cited with the most serious violations.

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.

The Radiological Health Program has initiated multiple efforts to improve the efficiency and effectiveness of the program with a focus on high-risk products. FDA proposed amendments to its regulations of electronic product reporting to better align the medical device and radiological health programs by reducing overlapping requirements. The program engaged with Customs and Border Protection and major online distributors to identify and prevent sale of non-compliant products that emit unsafe levels of radiation. For example, the program undertook a comprehensive approach to address widely distributed Ultraviolet-C germicidal wands that emit hazardous levels of radiation through laboratory analysis of product purchased undercover, regulatory action requiring manufacturers to refund/replace/repair, and public safety messaging advising consumers to not use the unsafe product.

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 x-ray imaging modalities, promote the use of international consensus standards, and promote the use of alternative technologies when appropriate. The Devices Program actively seeks to address safety issues and incorporate internationally accepted performance requirements and testing methods to enhance product safety through standards. Recent accomplishments include incorporation of pediatric safety features in standards for computed tomography (CT), fluoroscopy, and general and dental radiography.

Health Equity

Unmet and unaddressed health conditions in diverse populations negatively impact the nation's overall health, with many patients and communities not being included in the medical device development and evaluation process. FDA has taken deliberate actions to advance the inclusion of diverse patients and their perspectives in the evaluation of medical devices, including conducting collaborative research studies to understand how racially and ethnically diverse patients interface with digital health technologies and assess how well instruments used to measure daily lived experiences perform in people of different backgrounds. FDA participates in multiple collaborative activities such as collaborative communities that are focused on cultivating equitable participation of diverse populations in the healthcare ecosystem. To further help mitigate health disparities, CDRH launched, as a strategic priority, an effort to advance health equity leveraging the potential power of digital health technologies.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
253203: Percentage of received Original Premarket Approval (PMA), Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon. (Outcome)	FY 2019: 90.57% in 180 days Target: 90% in 180 days (Target Exceeded)	90% in 180 days	90% in 180 days	Maintain
253204: Percentage of 180-day PMA supplements reviewed and decided upon within 180 days. (Outcome)	FY 2019: 96.76 % in 180 days Target: 95% in 180 days (Target Exceeded)	95% in 180 days	95% in 180 days	Maintain
253205: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. (Outcome)	FY 2020: 95.4% in 90 days Target: 95% in 90 days (Target Exceeded)	95% in 90 days	95% in 90 days	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% in 150 days Target: 60% in 150 days (Target Exceeded)	70% in 150 days	70% in 150 days	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 2022: 100.0% Target: 65% (Target Exceeded)	65%	65%	Maintain
252223: Percent of total received High Priority MDRs (Code Blue and Death adverse events) reviewed within 10 days during the year. (Output)	FY 2022: 81.44% Target: 80% (Target Exceeded)	85%	88%	+3%
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (Output)	FY 2022: 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 2022: 2,641 Target: 2,000 (Target Exceeded)	2,000	2,000	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 2022: 99% 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 2022: 92.1 % Target: 80% (Target Exceeded)	80%	80%	Maintain

Measure	Year and Most Recent Result/Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
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 2022: 74.2 % Target: 65% (Target Exceeded)	65%	65%	Maintain

The following selected items highlight notable results and trends from 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. In FY 2018, FDA exceeded all of its MDUFA III performance goals.

Code Blue MDR Review

This goal previously only included Code Blue MDR reports, which represent the most serious adverse events received. Starting in FY 2023 however, 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 85% of all High Priority MDRs within 10 calendar days of receipt in FY 2023 and will increase to 88% in FY 2024.

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 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
Original PMAs and Panel-Track Supplements (without Advisory Committee input)			
Workload [1]	40	51	51
Total Decisions [2]	52	62	62
Approved [3]	38	44	44
Original PMAs and Panel-Track Supplements (with Advisory Committee input)			
Workload	-	2	2
Total Decisions [2]	1	2	2
Approved	-	2	2
Modular PMAs			
Workload	93	95	95
Actions [4]	84	98	98
180-day PMA Supplements			
Workload	145	178	178
Total Decisions [5]	138	152	152
Approved	122	132	132
Real Time PMA Supplements			
Workload	267	249	249
Total Decisions [6]	246	250	250
Approved	235	236	236
510(k) Premarket Notifications			
Workload	3895	4,595	4,595
Total Decisions [7] (SE & NSE)	3295	3,736	3,736
Cleared [9] (SE)	3134	3,634	3,634
Humanitarian Device Exemptions (HDE)			
Workload	2	3	3
Total Decisions [2]	2	2	2
Approved	1	2	2
Investigational Device Exemptions (IDE)			
Workload	331	355	355
Total Decisions [8]	338	381	381
Approved	183	196	196
Investigational Device Exemption Supplements			
Workload	1,717	1,823	1,823
Closures [10]	1,743	1,799	1,799
Pre-Submissions			
Workload	3,130	4,330	4,540
Closures [11]	3,057	4,213	4,398
De Novo			
Workload	82	70	70
Total Decisions [14]	61	55	55
Granted	26	30	30
Standards			
Total Standards Recognized for Application Review	1,464	1,480	1,510
Medical Device Reports (MDRs) [12]			
Reports Received	3,874,572	4,410,848	5,293,017
Analysis Consults [13]	577	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 -
[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.
[5] Total Decisions' include approval, approvable, approvable pending GMP inspection, and not approvable. (Decision Cohort)
[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
[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 signals in MDR
[14] Total Decisions include granted, declined, and withdrawal – regardless of the fiscal year received. (Decision Cohort)

Figure 45 - CDRH Workload and Outputs

Field Devices and Radiological Health Program Activity Data (PAD)			
Field Devices and Radiological Health Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***1,984***	***2,439***	***2,439***
Bioresearch Monitoring Program Inspections	215	300	300
Pre-Market Inspections	34	60	60
Post-Market Audit Inspections	20	35	35
GMP Inspections	1,062	1,300	1,300
Inspections (MQSA) FDA Domestic (non-VHA and VHA)	642	750	750
Domestic Radiological Health Inspections	59	65	65
Domestic Field Exams/Tests	32	45	45
Domestic Laboratory Samples Analyzed	123	170	170
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS [1]	***65***	***620***	***620***
Foreign Bioresearch Monitoring Inspections	3	14	14
Foreign Pre-Market Inspections	4	30	30
Foreign Post-Market Audit Inspections	5	20	20
Foreign GMP Inspections	41	550	550
Foreign MQSA Inspections	1	14	14
Foreign Radiological Health Inspections	20	50	50
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,049***	***3,058***	***3,058***
Import Field Exams/Tests	18,563	22,000	22,000
Import Laboratory Samples Analyzed	503	670	670
Import Physical Exam Subtotal	**19,066**	**22,670**	**22,670**
Import Line Decisions	25,205,483	25,961,648	26,740,497
Percent of Import Lines Physically Examined	0.08%	0.09%	0.08%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS [2]	***7,065***	***7,090***	***7,090***
Inspections (MQSA) by State Contract	7,029	7,050	7,050
GMP Inspections by State Contract	36	40	40
State Contract Devices Funding	$124,724	$127,218	$129,763
State Contract Mammography Funding	$10,590,612	$10,696,518	$10,803,483
Total State Funding	**$10,715,336**	**$10,823,737**	**$10,933,246**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***9,114***	***10,148***	***10,148***

[1] The FY 2021 actual unique count of foreign inspections includes 6 OGPS inspections (6 for China)

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.

3 Domestic MQSA Non-VHA and VHA Inpsections have been combined into one output line.

[4] ORA is currently evaluating the calculations for future estimates.

[5] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

[6] Count of "Third Party" Device Inspections (not included in Overall counts above) Foreign 4 and Domestic 3

Figure 46 - Field Devices and Radiological Health Program Workload and Outputs

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 generally 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.
- Use biomarkers—biological indicators of disease—to foster precision/personal medicine.
- 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)

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
National Center for Toxicological Research (Budget Authority)	66,702	66,634	70,391	76,919	80,154	3,235
FTE	296	308	276	286	286	---

Figure 47 - NCTR Funding History Table

The FY 2024 President's Budget for the National Center for Toxicological Research is $80,154,000, of which, all is budget authority. The budget authority increased by $3,235,000 compared to the FY 2023 Enacted Budget. The FY 2024 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. 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.
- Use biomarkers—biological indicators of disease—to foster precision/personal medicine.
- Understand the risks and benefits of nanomaterials used in FDA-regulated products.
- Provide FDA with data to support the Agency's COVID-19 response.
- 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.
- Provide data surrounding understudied populations such as 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 2024 President's Budget: NCTR *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Enacted	**76,919**
FY 2024 Budget Authority Changes	**3,235**
Investing in Core Operations - Crosscutting	**2,766**
Enterprise Data and IT Modernization	116
Public Health Employee Pay Costs	2,575
OC Regulatory and Mission Support	75
Other Adjustments	**469**
Comparability Adjustment	469
FY 2024 Budget Net Total: NCTR	**80,154**

Figure 48 - NCTR Budget Authority

Crosscutting: $2.8 million

Public Health Employee Pay Costs: +$2.6 million

Center: +$2.6 million

The FY 2024 Budget provides $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTEs funded through budget authority. Within NCTR, $2.6 million is provided for pay costs.

OC Regulatory and Mission Support: +$75,000

Center: +$75,000

The FY 2024 Budget provides $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that

FDA's programs operate effectively, efficiently, and are well coordinated. Within NCTR, $75,000 is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$116,000

Center: +$116,000

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $116,000 for the NCTR, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

As FDA's only dedicated research center, NCTR enhances FDA's basis for science-based regulatory decisions by conducting collaborative research to support of FDA, NCTR enhances FDA's basis for science-based regulatory decisions by conducting collaborative research with the FDA Product Centers and academia. The recent accomplishments and planned research represented in this narrative exemplify NCTR's support of the FDA product centers in emerging priorities, particularly the Focus Areas of Regulatory Science[72]. NCTR is aligned under FDA's Office of the Chief Scientist (OCS) and harnesses research data to help FDA make better-informed regulatory decisions. NCTR's goal is to promote public health by conducting research that supports product centers and ensures the safety and efficacy of FDA-regulated products. 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.

Artificial Intelligence (AI)

AI, an FDA and NCTR focus area, provides tremendous opportunities to modernize tools and technologies that assist FDA in fulfilling its mission. 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 serve to improve public health and expedite FDA review.

In support of FDA's AI efforts, NCTR created AI4TOX — an FDA program that aims to apply AI methods to develop new tools such as[73]:

- **AnimalGAN** aims to predict animal-toxicology data for untested chemicals through learning models that leverage existing animal data. A paper describing this effort was published in FY 2022 in Toxicological Sciences. In FY 2023 and FY 2024, NCTR will conduct research to extract more interpretable information from the AnimalGAN models to improve their regulatory application.
- **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. This collaboration with CDER is aimed at supporting the IND review process. A paper

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

[73] For more information, please visit: Artificial Intelligence | FDA

describing initial efforts was published in Frontiers in Artificial Intelligence. In FY 2023, continued research efforts will focus on development of models to predict cardiotoxicity and mutagenicity of drug products.

- **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. 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.
- **PathologAI** is an effective and accurate framework for analysis of histopathological data from animal studies to aid the use of digital pathology in preclinical application. A paper is being prepared to describe the overall PathologAI framework. Future efforts will include the mining of the relationship between genomics data and histopathological data to discover the molecular mechanisms underpinning histopathological responses.

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[74],[75]. If true, this can cause significant harm to minority patients with heart failure. 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.

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

The FDA PTR[76] describes a framework where the agency decision-making process is progressively informed by novel non-animal testing methods. 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, comparative assessments between traditional whole animal-based testing and emerging organ-on-a-chip technologies will help determine model strengths and shortcomings. Moreover, the translation and applicability of emerging organ-on-a-chip technologies with human biological responses must be established. This type of research will inform and empower regulators, thus protecting public health. The use of biomarkers and organ-on-a-chip technology are specific examples of how NCTR is supporting the PTR and contributing to Advancing Alternative Methods at FDA.

[74] For more information, please visit: Identification of Racial Inequities in Access to Specialized Inpatient Heart Failure Care at an Academic Medical Center | Circulation: Heart Failure (ahajournals.org)

[75] For more information, please visit: Hidden in Plain Sight — Reconsidering the Use of Race Correction in Clinical Algorithms | NEJM

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

- Supporting FDA PTR - Biomarkers
  In further support of the PTR focus areas, NCTR scientists are evaluating biomarkers to detect certain disease states, such as brain damage, at an earlier stage. The FDA has identified biomarkers as a Focus Area of Regulatory Science: Biomarkers. NCTR is currently investigating the possibility of detecting biomarkers of neurotoxicity using Magnetic Resonance Imaging (MRI), which could result in earlier, non-invasive detection of neurological disorders. Another possible application is safety assessments of regulated products, providing 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.

  NCTR scientists are also evaluating biomarkers for diagnosing the onset of prostate cancer. The standard Prostate-Specific Antigen (PSA) test for prostate cancer is problematic because of false positive/negative results. Despite this problem, PSA testing is still used because there are currently no known biomarkers for diagnosis. The results from this study will contribute to existing tests for prediction of prostate cancer risk and possibly lead to new treatments such as gene therapy. A publication summarizing this work has been accepted in *Cancer Genomics and Proteomics*. Biomarker research is also underway for drug-induced liver injury (DILI), cardiotoxicity and Alzheimer's disease.

- Supporting FDA PTR – Organ-On-A-Chip Technology
  Novel non-animal and human-specific technologies, like organ-on-a-chip technology for disease modeling is a top priority for research organizations like National Institutes of Health (NIH) and FDA-regulated industries. One chip technology currently being assessed at NCTR is brain-on-a-chip. Successfully implementing a translational model could be of great use to the Agency when assessing regulated products for the treatment of neurological disorders such as Alzheimer's disease. An Alzheimer's disease model would allow FDA to analyze the effects of potential drugs, biologics, and medical devices being developed for treatment of this debilitating disease. Moreover, this model would provide a screening platform to assess the potential neurotoxic effects to a "healthy" brain for any drug, biologic, or medical device under consideration by the Agency. This project will continue into FY 2024.

  Another chip technology currently under review 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 ability to predict idiosyncratic DILI— a treatment-related rare disease in which the molecular mechanisms, predictability, and mitigation approaches remain unclear. 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 the existing DILI biomarkers to help improve drug safety and promote public health. A recent paper describing this work was published in Current Protocols. A new protocol is being developed to qualify 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.

NCTR is also investigating testes-on-a-chip technology for its ability to be used in reproductive toxicology testing for safety assessment of drugs. Testes-on-a-chip is also being studied to investigate antiviral countermeasures for emerging threats like Zika virus. These studies are slated to continue into 2025.

Nanotechnology

The NCTR Nanotechnology Core Facility (Nanocore) supports collaborative research within FDA and research between FDA and other government agencies and universities. This work provides information on nanomaterial characterization and the safety of products containing nanomaterials in FDA-regulated products. This data is also used to establish much needed standards for use by stakeholders developing nanotechnology products. Nanomaterials are used in many FDA-regulated products — to date, over 970 drug products that contain nanomaterials have been submitted to FDA, with over 77 products approved for clinical use. Studies being conducted in the Nanocore help FDA to better assess nanomaterial-containing products' safety and efficacy. Examples are listed below:

In coordination with CDER, NCTR is studying how generic drug products containing nanomaterials disperse to different parts of the body in animal models. With OCS Nanotechnology Collaborative Opportunity for Research Excellence in Science (CORES) grant support, NCTR is conducting work investigating epigenetic effects of nanomaterial on human cells. An Office of Women's Health supported project on sex-based differences for immunotoxicity of nanomaterial is also in progress.

Nanotechnology standards development is vital for industry and FDA in advancing the translation of innovative products to market and commercialization. With support from the FDA product centers, National Institute of Environmental Health Sciences, Division of Translational Toxicology, National Institute of Standards and Technology, other government agencies, academia, and industry stakeholders, the Nanocore is actively pursuing research that supports international documentary standards development and review of draft standards from the International Organization for Standardization TC229, ASTM International E56, Organization for Economic Cooperation and Development Working Party on Manufactured Nanomaterials committees on nanotechnology. In FY 2022, scientists from the Nanocore developed four test method standards in nanotechnology that were published by the ASTM International:

E3297-21 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography (HPLC) with a Charged Aerosol Detector (CAD)

E3323-21 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using High Performance Liquid Chromatography (HPLC) with an Evaporative Light-Scattering Detector (ELSD)

E3324-22 Standard Test Method for Lipid Quantitation in Liposomal Formulations Using Ultra-High-Performance Liquid Chromatography (UHPLC) with Triple Quadrupole Mass Spectrometry (TQMS)

E3351-22 Standard Test Method for Detection of Nitric Oxide Production In Vitro

The Nanocore is working on a proposal to develop high- priority standards identified by the stakeholders such as FDA product centers, international regulators, industry, other government agencies, and academia. They include test methods for quality assurance and in-vitro test method standards that can minimize testing in animals. International Test Method Standards are an

invaluable resource for both FDA and industry to protect and promote public health. These standards will increase predictability, streamline pre-market review, and facilitate new product entry to market.

Through sponsorship with Asia Pacific Economic Cooperation (APEC), Oceans and Fisheries Working Group (OFWG) an international workshop on 'Nanoplastics in Marine Debris in APEC Region' was held in FY 2022. A workshop summary report was published. The Nanocore is planning to characterize polymers in support of a database development to enable identification and quantitation of complex micro nanoplastics mixtures and contaminants from the environment, food, and seafood. These activities will inform future collaborative work on micro nanoplastics at FDA and will be conducted in collaboration with other agencies and stakeholders.

In late FY 2022, CDER's Small Business and Industry Assistance collaborated with NCTR and the Nanotechnology Task Force to organize the FDA NanoDay Symposium 2022. The symposium, open to the public, addressed the drug development of products that contain nanomaterials in their formulation and presented reviewer perspectives on laboratory efforts to facilitate further understanding of challenges to manufacture products that contain nanomaterials.

Over 3,500 participants and registrants from 97 different countries attended virtually as speakers addressed topics.

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). FDA's concerns are summarized online (Focus Area: Quality of Compounded Drugs | FDA.) NCTR is currently 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.

Another compounding-related study at NCTR, in collaboration with CDER, is seeking to characterize the cellular toxicity of compounded triamcinolone-moxifloxacin (Tri-Moxi), a common anti-inflammatory drug used after cataract surgery. An 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. This 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 (triamcinolone acetonide, moxifloxacin, poloxamer 407, methylparaben, and propylparaben), the impact of compounding procedure, and potential relevant synergistic effects. The results from this study will be used by FDA to draft compounding risk alerts and/or guidance about selecting and using excipients in compounded formulations, especially when those excipients are used in amounts that significantly exceed those found in approved products. This research will continue into FY 2024.

COVID-19 Response

In support of FDA's Medical Countermeasures Initiative, NCTR has published 15 peer-reviewed scientific publications related to SARS-CoV-2, the virus that causes the illness known as COVID-19, since FY 2021. These publications provided important data needed by FDA and its stakeholders to best address the ever-evolving challenges associated with the current pandemic. In addition, in collaboration with the Center for Biologics Evaluation and Research (CBER), CDER, the Center for Devices and Radiological Health (CDRH), and CFSAN, NCTR has 25 active projects related to COVID-19 and 6 more projects in various phases of development. Moreover, NCTR is funding a SARS-CoV-2 study at both CBER and CDER to further the FDA's response efforts.

In collaboration with CDER, CDRH, NIH, and the National Center for Advancing Translational Sciences (NCATS), NCTR scientists are also conducting research using AI to identify drug candidates that can be repurposed for use in COVID-19 treatments. This research will extend into FY 2023 and FY 2024.

To combat the COVID-19 pandemic, physicians need to use safe drugs for COVID-19 patients. An ongoing NCTR project aims to investigate the safety of drugs that have been used to treat COVID-19 patients, using adverse events from real-world data, including data from Twitter and the FDA Adverse Event Reporting System (FAERS). NCTR scientists previously analyzed the adverse events in the FAERS for the drugs used for COVID-19 treatment in clinical practices and generated drug safety metrics[77]. Literature on pharmacovigilance suggest that social media platforms like Twitter could be a rich source of real-world information on drug usage and safety. Therefore, NCTR will analyze adverse events from Twitter using big-data analytics and AI. Over 200 million tweets related to COVID-19 from 2020 to 2022 have been collected. The generated drug safety metrics could serve as a tool to assist the selection of safe drugs for COVID-19 patients in clinical practices. Results for this research are expected in FY 2024.

NCTR scientists developed a method to monitor the presence of SARS-CoV-2 and its genetic variants in local community wastewater in Little Rock and Pine Bluff, Arkansas and correlated these data with COVID-19 clinical cases. Using this method, researchers were able to identify the SARS-CoV-2 variants (e.g. Delta, Omicron) in the wastewater that were responsible for epidemic outbreaks. The same variants were found in COVID-19 patients in Arkansas during the same period and the viral titers found in the wastewater correlated with the number of COVID-

[77] For more information, please visit: Informing selection of drugs for COVID-19 treatment through adverse events analysis | Scientific Reports (nature.com)

19 cases. These findings support the use of wastewater surveillance as a reliable complementary tool for monitoring SARS-CoV-2 and its genetic variants at the community level and can serve as an early indicator of viral spread and new variants. NCTR scientists are collaborating with the Arkansas Department of Health and University of Arkansas for Medical Sciences to apply these methods to the local public health system. A paper summarizing these finding was published in November 2022 in Science of The Total Environment. Wastewater analysis can detect an increasing number of variants. This is important because strains like BA.5 evade immunity from patients with previous COVID-19 infections and/or vaccinations and are therefore more easily spread. This project is expected to continue through FY 2023.

Cannabis-Derived Products such as Cannabidiol (CBD)

FDA recognizes the opportunities that cannabis or cannabis-derived compounds have for wide-spread 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[78] and that may put the health and safety of consumers at risk[79]. Since 2015, FDA has sent numerous warning letters to various companies who claim unsubstantiated benefits for cannabis-derived products[80], with 16 warning letters already 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[81]. 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 following efforts.

In collaboration with the CFSAN, NCTR scientists are using laboratory analytical testing results and artificial intelligence with online data to build new capabilities to evaluate the quality profile of CBD products. Overall, the results of this analysis will inform regulatory decision making regarding the safety of CBD. If successful, this project will also create a process that can be applied to multiple consumer product sampling projects and initiatives across the FDA. This research is expected to continue into FY 2024. In another collaboration with CFSAN, NCTR scientists are conducting research that will provide information concerning toxic effects of CBD and its main metabolites on the male reproductive system by using human somatic-cell models. This study will investigate and compare the underlying mechanisms of how CBD and its main metabolites negatively influence the male reproductive system in mouse and human reproductive-cell models. This information will help evaluate the predictive value of animal models, such as rodents—which metabolize CBD differently from humans. It also will help the FDA better define safety concerns with CBD and provide useful information to the public regarding the use of this cannabinoid. This research is expected to continue into FY2024.

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

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

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

[81] 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

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) of CBD in rats after applying CBD-containing oils and creams to the skin. The findings from this study are expected to assist CFSAN assess the safety of CBD and hemp-derived cosmetics for human use. This work will continue into FY 2024.

In collaboration with the OCS, CDER, and CFSAN, NCTR researchers continue to examine the effects of CBD exposure during perinatal development in rats. The effects from early exposure will be evaluated throughout adulthood and include: changes in motor function and reflexes; social and anxiety-like behavior; learning, memory, and complex cognition; changes in brain chemistry and immune function. These assessments are being complemented by further work at NCTR evaluating the effects of CBD in other organs, including the liver. The pharmacokinetics of CBD are also being characterized in rats orally exposed to CBD during development. This work is being conducted with the support of CFSAN, the Center for Veterinary Medicine, and the OFPR through the FDA Cannabis Products Committee. A full publication is expected to be submitted in FY 2023, providing valuable information that currently does not exist or is unavailable publicly.

Antimicrobial Resistance (AMR)

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[82]. The effects of the COVID-19 pandemic have had on combating antimicrobial-resistance (AMR) has been tremendous. Nearly 40% of the people who died from AMR infection became infected while in the hospital[83]. AMR is also included as a Focus Areas of Regulatory Science: Antimicrobial Resistance. Below are a few examples of NCTR efforts to support AMR.

A newly initiated AMR project at NCTR seeks to use computer modeling to design and test therapeutics suitable to combat AMR and multi-drug resistant (MDR) bacteria. The scientists will identify potential drug candidates that can limit or inhibit key microbial functions which control negative patient response to infection. In addition, this research will develop new therapeutics that limit damage from infectious diseases caused by over-or under-active responses to infection. The multifaceted selection process to target both AMR and MDR bacteria will focus on protecting the most vulnerable communities at the global level, both in the U.S. and internationally.

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 are targeting the understanding of factors that increase the ability of resistance plasmids to be transmitted among bacteria spreading AMR. A recent publication describing this work can be found in Microorganisms.

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

[83] For more information, please visit: COVID-19 & Antibiotic Resistance | CDC

Opioids

Drug overdose is the leading cause of death of Americans under the age of 50, with 74.8% of these deaths attributable to opioids, according to 2020 data from the CDC[84]. FDA's approach to reducing the misuse and abuse of opioids is outlined in various guidance[85]. 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.

To aid FDA in evaluating a product's potential for abuse, NCTR developed a computational model to assess the structure of addictive chemicals. This model improves understanding of the structural requirements associated with strong addiction potential and is expected to allow an accurate prediction of this potential for opioids, cannabinoids, and other structurally diverse chemicals. This technology may be used to prioritize the testing of chemicals with strong addiction potential (such as synthetic opioids and cannabinoids) or predicting abuse potential of new drugs, both shortening the FDA regulatory-review process. A related FY 2022 publication can be found in the Journal of Molecular Structure.

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, or medication-assisted treatment (MAT), is considered best practice for the mother and the baby. These drugs decrease withdrawal symptoms in the pregnant woman and often lead to better health outcomes for the infants, but they still carry risks for the developing fetus. A flood of illicit synthetic opioids has been seen during the pandemic and has exacerbated the opioid crisis in the U.S. 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 plans to initiate a 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 rodent model of MAT exposure that will simulate newborns that are weaned off opioids and then conduct a full study of long-term effects on offspring development, which will include assessing the contribution of maternal care to offspring outcomes. The project is nearing approval and is expected to last into FY 2025.

A closely related NCTR opioid study entitled, "Assessing the effects of methadone or buprenorphine and their combined use with cannabinoids on human neural stem cells" is ongoing in FY 2023. This study will describe the molecular, cellular, and electrophysiological changes caused by each drug and their combinations, during early stages of brain development. It will also determine the time-course and dose-dependent effects of each drug, therefore supporting development of strategies to guide the safe use of methadone and buprenorphine drugs during pregnancy. This project will continue into FY 2024.

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

The focus of NCTR's Virtual Center of Excellence for Perinatal and Maternal Pharmacology and Toxicology—also known as the FDA Perinatal Health Center of Excellence (PHCE)—is the perinatal period (the period-of-time including maternal, premature, neonatal, and pediatric periods, as well as development throughout childhood) which is vastly understudied. The PHCE

[84] For more information, please visit: Death Rate Maps & Graphs | Drug Overdose | CDC Injury Center

[85] For more information, please visit: https://www.fda.gov/drugs/information-drug-class/opioid-medications

funds research 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 pregnancy and in premature infants, as well as newborns. Current PHCE projects have principal investigators representing FDA's CDER, CBER, CDRH, CFSAN, and NCTR.

An ongoing PHCE study, "Evaluation of drug toxicity on placenta immunity using a microphysiological human placental barrier model," is expected to finish in FY 2023. The goals of this project are to:

- Provide information to guide the safe and effective use of drugs during pregnancy
- Evaluate new prediction tools for the risk assessment of drugs in terms of placental immunity
- Provide information for FDA benefit-risk assessment and regulatory decisions for a new drug with potential use in pregnant women
- Contribute to the format and content of pregnancy and lactation labeling
- Prevent illness and diseases in infants and children

In November 2022, 13 new PHCE projects were selected to be awarded. Including the 4 ongoing projects, the PHCE will be funding 17 projects in FY 2023. The new projects include primary investigators from CBER, CDER, and NCTR. Topics for these new projects include, but are not limited to:

- ZIKA virus mRNA biomarkers
- Computer-based models for lactation
- Perinatal cannabinoid CNS activity and toxicity

PERFORMANCE

NCTR's performance measures focus on research to advance the safety of FDA-regulated products, to develop an FDA science base for alternative assays, discovery of perinatal and maternal therapeutic solutions, FDA's COVID-19 response, and cannabis research to protect and improve the health of the American public as represented by the following table:

Measure	Most Recent Result / Target for Recent Result	FY 2023 Target	FY 2024 Target
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates. (Output)	FY 2022: Preliminary data on cannabidiol (CBD) exposure in the developing brain was presented at the 61st Annual Society of Toxicology meeting in March 2022. (Target Met)	Support CDER compounding efforts by characterizing compounded triamcinolone-moxifloxacin. Report preliminary findings on the effects of drug toxicity using a micro-physiological human-placental barrier model.	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 capability for microbiome assessment to improve the prediction of safety

Measure	Most Recent Result / Target for Recent Result	FY 2023 Target	FY 2024 Target
			assessment of FDA-regulated products.
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. (Output)	FY 2022: Development of a Pregnant Woman Artificial Intelligence (AI) Modeling Suite has been initiated with an antihypertensive drug as the first case study. (Target Met) FY 2022: In collaboration with University of Tennessee Health Science Center scientists provided an assessment and characterization of SARS-CoV-2 animal model, focusing on determining the appropriate viral dose in non-pregnant animals. (Target Met)	In collaboration with CBER, report findings associated with Zika virus utilizing a micro-physiological system.	Develop explainable AI models to facilitate FDA application of AI and improve regulatory guidance to evaluate AI-centric products. Provide preliminary results on hazard assessment data for SARS-CoV-2 infection during pregnancy and early development.
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize therapeutic care. (Output)	FY 2022: Research was performed to identify potential biomarkers for the onset of prostate cancer. A manuscript was drafted in FY 2022 and published in early FY 2023. (Target Met)	In collaboration with CDER, improve minimally invasive MRI biomarkers to modernize drug neurotoxicity testing which may ensure that safer drugs reach the market faster. Characterize the development of “brain-chips" which simulate Alzheimer’s disease and compare them to healthy brain-chips.	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.
264101: Develop risk assessment methods and build biological dose-response models in support of food protection. (Output)	FY 2022: Preliminary findings regarding nanomaterial interaction with the gastrointestinal tract have been reported. A book chapter related to this work was published in July 2022. (Target Met)	Report preliminary findings on evaluating the virulence potential of bacterial pathogens using 3D tissue-culture model systems.	Generate an *E. coli* virulence gene data set for use in the development of the *E. coli* virulence gene database.
263104: Use new omics technologies to develop	FY 2022: A database of opioid agonists/antagonists	Support CBER improvement of	Provide preliminary results on the

Measure	Most Recent Result / Target for Recent Result	FY 2023 Target	FY 2024 Target
approaches that assess risk and assure the safety of products that FDA regulates. (Output)	was developed to assist in alternative pain management therapies. (Target Met)	pediatric vaccines by studying whether maternal obesity impacts vaccine outcomes.	development of a method to analyze genetic material to detect specific microorganisms from non-sterile pharmaceutical products.
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. (Output)	FY 2022: Initial data regarding a study to benchmark and compare computational and genomic predictive methods for toxicity for drug induced-liver injury (DILI) using AI-based methods was provided. A related FY 2022 publication can be found in *Frontiers in Artificial Intelligence*. (Target Met)	Report findings associated with Deep DILI which will compare computational and genomic predictive methods for DILI.	In collaboration with CDER, improve patient safety and drug efficacy by using AI and Natural Language Processing (NLP) on FDA drug labeling documents.

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

Advance the Safety of FDA-Regulated Products

NCTR research is vital to ensure the safety and effectiveness of the products that the FDA regulates. In FY 2022 researchers provided preliminary data on cannabidiol, better known as CBD, exposure in the developing brain. These data were presented at the 61st Annual Society of Toxicology meeting in March 2022. In FY 2023, NCTR will support CDER compounding efforts by characterizing compounded triamcinolone-moxifloxacin as well as providing preliminary findings on the effects of drug toxicity using a micro-physiological human placental barrier model. In FY 2024, NCTR researchers will provide preliminary results on the effects of methadone or buprenorphine (used during opioid detox) and their combined use with cannabinoids.

Science Base for Alternative Assays

NCTR continues to develop a science base to promote the FDA's move towards alternative assays. These efforts look to replace animal models with in vitro (i.e., cellular) or in silico (computer-based) models. In FY 2022, NCTR initiated the development of a virtual pregnant-woman modeling suite to support regulatory decisions using bioinformatics and artificial intelligence (AI). This work continues into FY 2023 with the goal that the pregnant-woman modeling suite will be the first-of-its-kind in the field of biological modeling, pregnancy health, and regulatory science. In FY 2023, NCTR scientists, in collaboration with CBER, will report findings associated with Zika virus utilizing a micro-physiological system. In FY 2024, NCTR is slated to develop explainable AI models to facilitate FDA application of AI and improve regulatory guidance to evaluate AI-centric products.

Maternal and Perinatal Medicine

Scientific expertise in perinatal and maternal health has long been a strength and focus of the NCTR. In FY 2019, NCTR implemented the Perinatal Health Center of Excellence (PHCE) to focus on this vastly understudied area of regulatory science and continues today. The PHCE focuses on the perinatal period (the period-of-time including pregnancy, childbirth, and infant/child development) and covers a broad range of research topics from chemical toxicology to new computer modeling methods. All PHCE projects have a common goal to fill knowledge gaps around perinatal safety and efficacy. In FY 2022, NCTR scientists in collaboration with the PHCE, reported preliminary findings related to COVID-19 effects on pregnancy and prenatal/postnatal development. In FY 2023, NCTR will support CBER with improvement of pediatric vaccines by studying whether maternal obesity impacts vaccine outcomes.

PROGRAM ACTIVITY DATA

National Center for Toxicological Research Program Activity Data (PAD)			
Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
Research Outputs			
Research Publications	146	148	150
Research Presentations	150	160	162
Patents (Industry)	14	13	14
Leveraged Research			
Federal Agencies (Interagency Agreements)	4	4	4
Nongovernmental Organizations	66	61	59

Figure 49 – 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 federal, state and local partnerships, and
- Information sharing with domestic and international regulatory and 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 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Office of Regulatory Affairs	**1,224,332**	**1,224,098**	**1,289,779**	**1,354,061**	**1,428,259**	**74,198**
Budget Authority	***1,123,417***	***1,130,376***	***1,165,610***	***1,227,968***	***1,287,381***	***59,413***
User Fees	***100,915***	***93,722***	***124,169***	***126,093***	***140,878***	***14,785***
FTE	**4,894**	**5,205**	**4,952**	**4,996**	**5,067**	**71**

Figure 50 - ORA Funding History Table

The FY 2024 President's Budget for the Office of Regulatory Affairs Program is $1,428,259,000 of which $1,287,381,000 is budget authority and $140,878,000 is user fees. The budget authority increases by $59,413,000 compared to the FY 2023 Enacted Budget. User Fees increase by $14,785,000.

BUDGET AUTHORITY

FY 2024 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 Enacted	**794,230**	**210,501**	**48,050**	**81,952**	**93,235**	**1,227,968**
FY 2024 Budget Authority Changes	**45,999**	**4,905**	**1,392**	**3,314**	**3,803**	**59,413**
Enhancing Food Safety, Nutrition & Cosmetics	**28,264**	**-**	**-**	**1,406**	**-**	**29,670**
New Era of Smarter Food Safety	5,249	-	-	-	-	5,249
Healthy and Safe Food for All	23,015	-	-	-	-	23,015
Animal Food Safety Lifecycle	-	-	-	1,406	-	1,406
Advancing Medical Product Safety	**-**	**2,300**	**-**	**-**	**-**	**2,300**
Advancing the Goal of Ending the Opioid Crisis	-	2,300	-	-	-	2,300
Investing in Core Operations - Crosscutting	**29,944**	**7,888**	**2,313**	**3,014**	**5,172**	**48,331**
Enterprise Data and IT Modernization	1,434	406	118	165	259	2,382
Public Health Employee Pay Costs	27,060	7,054	2,070	2,679	4,647	43,510
OC Regulatory and Mission Support	1,450	428	125	170	266	2,439
Other Adjustments	**(12,209)**	**(5,283)**	**(921)**	**(1,106)**	**(1,369)**	**(20,888)**
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)
Comparability Adjustment	4,005	349	102	346	630	5,432
FY 2024 Budget Net Total: ORA	**840,229**	**215,406**	**49,442**	**85,266**	**97,038**	**1,287,381**

Figure 51 - ORA Budget Authority

Food Safety: $29.7 million / 83 FTE

New Era of Smarter Food Safety: +$5.2 million / 3 FTE

Field: +$5.2 million / 3 FTE

The FY 2024 Budget provides $37.0 million for the New Era of Smarter Food Safety, including an increase of $5.2 million for ORA. The Budget builds on the funding requested in the FY 2023 Budget to continue progress towards the goals of the New Era of Smarter Food Safety.

Within ORA, FDA will fund the independent review of the ORA training process and help to fund development of the necessary infrastructures based on the findings. This includes mechanisms to ensure maintenance of Integrated Food Safety System (IFSS) personnel proficiency after training and to secure necessary partnerships to stand-up and implement the

governance structure and processes. ORA will also invest in identifying and implementing cutting edge and future practices, including technology tools that will modernize existing and future training courses for FDA and IFSS partners. Additionally, this funding will promote coordination and support for modernized retail foods operations in line with the New Era initiative, include further support for regulatory oversight of the expanding eCommerce market. ORA will hire three new FTE to help provide coordination and support to retail foods operations, including eCommerce to help ensure the safety of foods sold at restaurants and other foods establishments, along with support of the Voluntary National Retail Food Regulatory Program Standards.

Healthy and Safe Food for All: +$23.0 million / 75 FTE

Field: +$23.0 million / 75 FTE

The FY 2024 Budget provides $64.0 million for Healthy and Safe Food for All, including an increase of $23.0 million for ORA. The Budget builds on the funding requested in the FY 2023 Budget to continue progress towards the goals of the New Era of Smarter Food Safety. The FY 2024 Budget will help to modernize oversight of infant formula, empower consumers to make healthier food choices, reduce exposure to toxic chemicals, and implement new regulatory authorities for both cosmetics and dietary supplements. FDA will modernize infant formula oversight by hiring additional experts to stay current on innovations in infant formula production and to ensure continuous and rapid review of all new applications and adverse event reports. Funds will also support the immediate review of all inspection fundings and initiation of a rapid response when violations are identified.

This funding request will also provide long term investments and allow for greater oversight for infant formula. FDA is seeking additional investigators, both civil and criminal, to gain additional information about how much volume is coming through these modes and which manufacturers could be potentially producing counterfeit or fraudulent FDA regulated products. These resources would be used to enhance our infant formula complaint notification and response system and additional, dedicated foreign and domestic staff for investigations and compliance activities related to the domestic and foreign facilities. ORA has staff who are the clearance point and coordinators for all administrative warrants and actions and liaises with our Center counterparts to ensure coordination of evidence. Additional FTEs for this program will also perform internet investigations of fraudulent and tainted products, including performing undercover buys and the collection of samples for analysis. They will evaluate and execute compliance actions related to fraudulent and tainted products, while also working to develop and publish proposed regulations regarding infant formula.

The funding will also enhance ORA's scientific mission by providing additional resources to procure advanced analytical equipment and hire FTE to develop methods for identifying emerging chemical contaminates, such as PFAS, in FDA regulated products. These contaminates present unique challenges and ORA requires the appropriate equipment and expertise to support the Agency's risk assessment programs, such as the Total Diet Study.

Animal Food Safety Lifecycle: +$1.4 million / 5 FTE

Field: +$1.4 million / 5 FTE

The FY 2024 Budget provides $5.2 million for Animal Food Safety Lifecycle, including $1.4 million to ORA. The FY 2024 Budget will address the struggles in keeping pace with pre-market animal food ingredient reviews and overseeing the animal food industry as ingredients are combined, packaged, and sold as animal food, activities that have been historically underfunded. FDA will need to more than double current FDA inspections and double state contract inspections to meet our domestic FSMA animal food inspection frequency. We cannot take on the burden of increased inspectional oversight of animal food facilities without additional investments at both the Center, ORA, and state level to support the increased inspectional workload.

These resources will provide additional FTE to conduct FDA field activities such as animal foods inspections and working with our state regulatory partners. Domestic mutual reliance is a critical component of both FSMA, IFFS, and the New Era of Smarter Food Safety as it strengthens partnerships with states to ensure optimal use of resources and maximizes food safety oversight. Achieving domestic mutual reliance relies on building an integrated partnership that enables FDA and states with comparable regulatory public health systems to coordinate and leverage one another's work, data, and actions. This integrated approach with our trusted partners serves to meet the public health goal of a safe human and animal food supply. While the importance of this partnership is often highlighted publicly during an ongoing foodborne outbreak or other public health emergency, the underlying work to build these critical partnerships often goes unrecognized both at the state and national levels. State regulatory and public health infrastructure is eroding, and states will be unable to support integration and modernizing of their animal food programs without the support, cooperation, and partnership with FDA.

Medical Product Safety: $2.3 million / 5 FTE

Advancing the Goal of Ending the Opioid Crisis: +$2.3 million / 5 FTE

Field: +$2.3 million / 5 FTE

The FY 2024 Budget provides $23.0 million for Advancing the Goal of Ending the Opioid Crisis, including $2.3 million for ORA.

ORA is requesting funding to expand the current IMF initiative to interdict shipments of opioids, unapproved foreign drugs, counterfeit pharmaceuticals and health fraud related shipments. 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. Under the 2018 Omnibus Spending Bill FDA did hire additional compliance officers, but the increased volume has taxed our compliance staff to a greater extent than anticipated, and this requested increase would lessen the burden on the compliance officers, who are also responsible for compliance and enforcement action for other types of imported products and FSVP Inspections.

Under the current IMF initiative, ORA has multiple laboratory supported subcomponents, inclusive of unapproved foreign drugs, counterfeit pharmaceuticals, health fraud, opioid testing, establishment of IMF mobile laboratories, field deployable toolkit development, training and deployment, and sample analyses related to criminal investigations. As the program matures, additional resources will be required to meet the increased volume and complexity of the samples. Additional resources are required for management and support of new or existing analytical tools deployed for field use, development of new analytical methods or strategies,

accreditation/proficiency requirements and expansion of the safety program for the geographically diverse locations.

Compounding and Outsourcer inspections have added an investigational assessment for compounding of opioid and opioid products. This expanded investigation has involved tracking and tracing supply chain along with production activities at the compounding facilities. Additional resources are needed as the outsourcer inventory has grown and the products produced, and supply chains have become more complex. These same resources could assist in label review and subject matter assistance at the IMFs.

Crosscutting: $48.3 million / 16 FTE

Public Health Employee Pay Costs: +$43.5 million

Foods Field: +$27.1 million

Human Drugs Field: +$7.1 million

Biologics Field: +$2.1 million

Animal Drugs Field: +$2.7 million

Devices Field: +$4.6 million

The FY 2024 Budget includes $105.3 million in new budget authority to fully fund the anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTE funded through budget authority. Within ORA, $43.5 million is provided for pay costs.

OC Regulatory and Mission Support: +$2.4 million / 13 FTE

Foods Field: +$1.5million / 5 FTE

Human Drugs Field: +$428,000 / 2 FTE

Biologics Field: +$125,000 / 2 FTE

Animal Drugs Field: +$170,000 / 2 FTE

Devices Field: +$266,000 / 2 FTE

The FY 2024 Budget includes $15.8 million within the Office of the Commissioner to advance the highest priority Regulatory Capacity and Mission Support functions to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well coordinated. Within ORA, $2.4 million is provided for OC Regulatory and Mission Support.

Enterprise Data and IT Modernization: +$2.4 million / 3 FTE

Foods Field: +$1.4 million / 2 FTE

Human Drugs Field: +$406,000 / 1 FTE

Biologics Field: +$118,000

Animal Drugs Field: +$165,000

Devices Field: +$259,000

The FY 2024 Budget includes an increase of $10.0 million, for a total of $28.0 million, including $2.4 million for ORA, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both the Foods and Medical Product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

USER FEES

Current Law User Fees: +$14.3 million

Field Human Drugs: +$4.8 million

Field Biologics: +$363,000

Field Animal Drugs and Foods: +$90,000

Field Devices: +$279,000

Field Center for Tobacco: +$8.8 million

The Office of Regulatory Affairs Program request includes an increase of $14.3 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 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, and
- 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.

In FY 2022, ORA resumed a normal cadence core mission activities including domestic and foreign operations that support human food, animal food, and medical product safety.

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. It is estimated that ORA staff at IMFs physically inspect less than 0.06% of the packages that are presumed to contain drug products. Recognizing these hurdles, ORA is increasing existing resources and efficiencies, and is identifying innovative ways to expand its impact. In FY 2022, ORA reviewed more than 100,000 products coming through IMFs, an increase over FY 2021. ORA also continues to evaluate ways to streamline IMF processes, increase workspace, and make IT improvements that expand parcel review.

In FY 2020 in partnership with U.S. Customs and Border Protection (CBP), FDA established the first permanent space for laboratory scientists to conduct rapid field testing using specialized analytical equipment is in progress at the Chicago O'Hare IMFs. Plans are underway to establish satellite laboratories at additional IMF and courier hub locations, with Miami anticipated to be operational early in 2023. The satellite laboratory effort is expected to allow FDA import

investigators to review an increased percentage of parcels coming into the IMFs and to improve the kind of information that can be communicated with CBP.

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 who worked in an intensive care unit that provided care to critically ill patients with life-threatening neurological problems was discovered to have withdrawn fentanyl from vials and replaced it with saline so that it would appear as if none of the narcotics were missing. In July 2022, the nurse was sentenced to one year in federal prison. ORA is involved in several similar cases involving health care workers across the country.

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. As of September 30, 2022, ORA’s Operation Cyberpharma has led to 60 arrests, 26 convictions, and aided in the takedown of a major darknet marketplace, as well as the seizure of drug counterfeiting tools, counterfeit drugs, and more than $8.4 million in virtual currencies and other assets. Further arrests and seizures are anticipated in this ongoing operation.

Foreign Unannounced Inspection Pilot

In FY 2022 Congress provided FDA/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 November 2022, FDA has completed 35 inspections in India as part of the FUIP. The inspections conducted under the FUIP have allowed FDA to gain insights into the impact of notification type on FDA foreign inspections. ORA will increase the number of surveillance pilot inspections starting in January 2023 as we move into the next phase of the FUIP in India.

Travel demands and inspection complexities have presented some challenges in carrying out the FUIP as the inspections require more experience investigators and ORA continues to backfill and train new investigators. Currently, we do not have an anticipated date to initiate the pilot in China, as was included in the directive from Congress, due to China's restrictive and unpredictable travel policies that result from their zero-tolerance approach to COVID-19. ORA is committed to initiating inspections and extending the FUIP to China as soon as it is safe to do so.

Advanced Medical Product Manufacturing

At the start of FY 2022, ORA established an Associate Director of Advanced Medical Products Manufacturing position as an initial step in developing a formal advanced manufacturing and medical countermeasures program within ORA. This position engages with Centers and other agency offices to support and facilitate the adoption of innovative technologies and to establish a regulatory framework for advanced manufacturing. This position also is working to establish a

contract to enhance ORA's advanced manufacturing training for investigators to ensure inspectional readiness that is proportionate to advancements in medical products manufacturing. Additionally, ORA continues to engage with our foreign regulatory partners to maintain global awareness of industry and regulatory advancements.

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. Once finalized, FDA regulations will be more harmonized with requirements of the many countries that use ISO 13485 as a foundation for their device manufacturing quality requirements. ORA is using this opportunity to enhance our medical device inspection approaches to keep pace with these wide-ranging changes.

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. In FY 2022, the BIMO Program completed more than 900 domestic inspections and approximately 200 foreign inspections.

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, ORA's Biologics Program has exercised an important role in its oversight of manufacturers of biological products, including blood, vaccines, and 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 1,110 post-market surveillance activities in FY 2022, 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 ecommerce 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 (IF) recall and shortage crisis, ORA worked closely with state partners to leverage resources on IF 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. This allowed infant formula product needed to meet the needs of consumers into the United States provided certain requirements were met. 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. Currently ORA is developing a dedicated cadre of staff that will be responsible for conducting all domestic and international IF inspections and is also designing an IF workshop to modernize training for investigators.

Promoting an Integrated Food Safety System (IFSS)

ORA provides funding and programmatic support to SLTT regulatory jurisdictions to support robust oversight and ensure an IFSS. For example, in FY 2022, ORA awarded 86 contracts ($115.6 million total) to 45 state regulatory partners and Puerto Rico to enable approximately 13,000 inspections (including approximately 700 human food preventive controls inspections), site visits, and sample collections. In addition, the FDA awarded 199 cooperative agreements and/or grants to all 50 states and 12 stakeholder associations 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 six new Domestic Mutual Reliance Partnership Agreements with state programs, 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, e.g., by leveraging states' non-contract inspections 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 and while they are not a replacement for inspections, they provide important information that helps FDA maintain a level of regulatory oversight.

The use of RRAs to support oversight of drug manufacturing has 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 as well as received and evaluated surveillance reports for foreign work from mutual recognition agreements and the Pharmaceutical Inspection Co-operation Scheme (PIC/S) inspectorates. ORA also led the cross-agency working group that developed and issued a draft guidance for industry entitled, "Conducting Remote Regulatory Assessments." Additionally, ORA received and evaluated surveillance reports for foreign work from mutual recognition agreement partners and PIC/S inspectorates.

In FY 2022, due to continued challenges due to the global public health pandemic, the ORA Food Program collaborated with import operations to design a new approach that coupled RRAs, product sampling at the border, and importer inspections to provide an additional layer of regulatory oversight that did not previously exist. The agency has conducted 95 RRAs, 169 target sampling assignments, 16 inspections, eight warning letters, 20 import line refusals (a line is a distinct product, which may include one or numerous products, within a shipment), and 20 updates to import alerts as part of this program.

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 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 134 requests in FY 2022 and a total of 352 requests related to this authority. Confidentiality commitments enable this information sharing (limited in scope to drugs only) with the competent authorities for each European Union Member State.

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 328 local and state health departments. To date, ORA has received state inspection findings for more than 800 firms and is using the data to increase understanding of the inventory and streamline resource planning within ORA.

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.

IMPORT LINES BY PROGRAM AREA
FY 2015-FY 2024(Est.)

Program Area	2015	2016	2017	2018	2019	2020	2021	5 Yr Actual Percent Growth*	2021 Percent of Total Lines	2022	Estimate 2023	Estimate 2024
Foods	13,080,429	13,952,537	15,251,687	16,859,790	17,722,742	16,983,686	18,651,210	7%	39.86%	19,344,104	19,924,427	20,511,160
Cosmetics	2,930,682	2,939,034	2,625,555	2,729,584	2,762,411	2,350,216	3,060,422	1%	6.54%	3,152,235	3,246,802	3,344,206
Human Drugs	688,208	739,309	789,853	871,212	838,267	959,585	1,003,661	9%	2.15%	1,021,775	1,052,428	1,084,001
Animal Drugs & Feeds	416,860	446,903	426,484	456,684	481,684	493,192	550,811	8%	1.18%	572,292	589,461	693,081
Biologics	150,673	151,911	157,080	170,575	181,328	152,158	177,977	2%	0.38%	64,884	197,462	197,462
Medical Devices & Rad Health	17,252,283	18,757,725	20,584,138	22,291,902	22,967,758	22,512,049	25,521,999	6%	54.55%	25,521,999	27,308,539	27,308,539
Tobacco Products	16,680	32,972	199,066	281,097	280,901	275,261	263,943	15%	0.56%	229,389	240,858	252,901
Total	34,535,815	37,020,391	40,033,863	43,660,844	45,235,091	43,726,147	46,788,819	5%	100.00%	49,906,678	52,559,977	53,391,350

*Percent growth based on a five-year average of actuals from FY 2017 - FY 2021

**Get from Current FY PAD Table-under "Import Line Decisions"
***For finding Actuals for current FY go to "FYXX Program Activities Data" PDF
****For tobacco reference Leigh Kelsey's year end data

Table 1

Figure 52 - Number of Import Lines by Program Area: FY 2015 through FY 2024 (Est.)

ORA oversees food importers through establishment of the remote inspection protocol for Foreign Supplier Verification Programs (FSVP) inspections. As of November 16, 2022, ORA conducted 1,827 FSVP inspections of which 1,621 were conducted remotely and 206 were performed onsite. The FSVP has reached its fifth year of implementation and has worked throughout this time to educate industry during inspections, when discussing compliance actions, and through outreach and partnership with groups such as the Food Safety Preventive Alliance (FSPCA) on the requirements. As FDA moves into the fifth year, steps were taken to further refine the program by requiring the use of the Data Universal Numbering System (DUNS) number to identify firms in the supply chain and no longer recognizing the "UNK" catch-all designation that had been allowed. To this end, the program issued updated guidance, provided directed outreach to those transmitting "UNK," and collaborated with CBP to implement system changes. Through extensive communication to industry, the program was successfully launched with minimal impact to trade and has improved data quality.

For foreign firms in certain countries where FDA cannot routinely conduct inspections due to high-security risk, ORA and CFSAN developed a program to provide alternative oversight of foreign food facilities. This program leverages FDA's regulatory programs to ensure supply chain security and compliance with good manufacturing practices. This program combines data and information from FSVP inspections, importer seafood Hazard Analysis and Critical Control

Point (HACCP) inspection and import sampling programs to improve oversight coverage and mitigate potential public health risk(s). In FY 2022, the program was able to oversee the supply chain of 267 foreign food manufacturers that may not have received oversight due to being in areas of security concern. This includes 95 RRAs, 11 FSVP inspections, five import seafood HACCP inspections, and 169 targeted samples of these manufacturers.

ORA continues implementation of the Voluntary Qualified Importer Program (VQIP). On January 1, 2022, the VQIP application portal became available on www.fda.gov and remained open to accept completed VQIP applications through May 31, 2022. This year, FDA received six VQIP applications for FY 2023 benefits, including extensions from all four approved applicants from FY 2022. The associated information for all importers approved for participation in this program may be found in the FDA Data Dashboard under 'Approved VQIP Importers.

Leveraging Laboratory Capabilities

FDA laboratories support the Agency's mission by performing scientific testing on regulated products, conducting applied research, and supporting inspectional and compliance operations, as well as criminal investigations. Analyses performed in the laboratories include whole genome sequencing (WGS), which is used for epidemiological trace-back based on genetic fingerprinting, and the use of advanced vibrational spectroscopies, nuclear magnetic resonance, separation systems, and mass spectrometry systems to detect and identify unapproved drugs and chemical contaminants in a vast variety of products including human and animal foods, vaping liquids, and drugs. 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 commodity specialized laboratory programs at 12 locations across the United States and Puerto Rico and is in the process of establishing satellite laboratories at select IMFs.

Analytical excellence has played a pivotal role in FDA's response to recent public health emergencies such as the opioid crisis, vaping related deaths, foodborne illnesses, adverse events associated with quality and integrity of infant formula, pharmaceuticals, medical devices, and counterfeit, falsified, and substandard products. New complex consumer products entering the marketplace present unique risks and analytical challenges requiring a responsive, flexible laboratory network. The active research portfolio and technical training programs of ORA laboratories provide analytical readiness to protect the public health from current and future threats.

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 is conducting a pilot program that uses artificial intelligence (AI) to strengthen the ability to predict which shipments of imported foods pose the greatest risk of violation and use that information to improve targeted import review resources. In FY 2022, FDA continued to evaluate AI and machine learning to strengthen import screening and better facilitate movement of safe foods into the United States. The AI seafood pilot launched in August 2022 using a new model to target certain imported seafood. The pilot will be completed in FY 2023, at which time

FDA will conduct a comprehensive analysis will be conducted to determine utility and effectiveness.

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. In FY 2022 ORA surveillance revealed several products alleging to be honey marketed with male sexual enhancement claims. ORA conducted investigations and undercover purchases on 12 such products. FDA lab analysis found all 12 to contain either sildenafil or tadalafil, the active pharmaceutical ingredients in the FDA-approved prescription drugs such as Viagra and Cialis. None of these products listed sildenafil or tadalafil on the label. These products can cause serious harm or death in patients taking nitrates as part of a treatment program. The agency issued five warning letters to firms marketing these products and issued 11 public notifications.

ORA, through the Office of Criminal Investigations (OCI), 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 2022, criminal investigations led to 145 arrests and more than $638 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, 2022, ORA opened approximately 167 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 October 2020, leadership from FDA, CBP, and the U.S. Immigration and Customs Enforcement, Homeland Security Investigations (ICE-HSI) signed a Memorandum of Understanding (MOU) to stop harmful products that pose a threat to public health and attempt to enter the United States through IMFs. To enhance the collaboration and information sharing outlined in this MOU, FDA and CBP have agreed upon a National Opioid Strategy, which launched in FY 2022. This strategy targeted unapproved drugs and illegal opioids in the IMF and among couriers. In collaboration with CBP, the operation successfully stopped over more than 390,000 tablets and capsules of unapproved drugs (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 82% of violative refused drug products in FY 2022, an increase from the 77% refusal rate in FY 2020.

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 the FD&C act that FDA has jurisdiction over products containing nicotine from any source, including non-tobacco nicotine products. In FY 2022, ORA completed 135 inspections of domestic tobacco product manufacturers, seven foreign inspections, 207 investigations, and one 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. As part of the implementation strategy, ORA and CTP work together to focus import surveillance activities of tobacco products, including flavored, cartridge-based ENDS products. The enforcement strategy was updated to include PMTA requirements for non-tobacco nicotine products in April 2022. The heightened surveillance of indicated ENDS products has led to an increasing yearly average when compared to the year prior. Since implementation, FDA has examined more than 3,900 lines (a line is a distinct product, which may include one or numerous products, within a shipment) of ENDS products, and found 1,480 (or 38%) to be violative. In FY 2022, FDA refused admission to 111 violative product lines and worked with CBP to prevent violative ENDS products from reaching the consumer.

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 CURES. At this time, ORA is working to re-obtain Direct Hire Authority for investigators which expired in October 2021, to decrease challenges related to hiring. Even with these challenges, ORA has made great strides in creating 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 2022 was to hire 192 full-time equivalents (FTEs). ORA met the hiring goal, gaining 229 FTEs, and maintained a 9.01% attrition rate, which is slightly above the FDA's average attrition rate of 8.7%.

In support of our public health mission, ORA's Office of Training Education and Development (OTED) provides free training to our SLTT regulatory partners – a critical part of developing and maintaining a regulatory workforce across the country. In FY 2022, ORA held a total of 245 courses for 5,215 students through virtual instructor- led training, classroom, and blended

training courses. In FY 2022, ORA implemented independent course delivery and train-the-trainer programs for SLTT regulatory partners to support the IFSS training system.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2022: 97.7% 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 2022: 93.4% 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 2022: 96.7% 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 2022: 92.1% 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 2022: 72.7% 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 2022: 56.8% Target: 55% (Target Exceeded)	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 2022: 92.9% 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 2022: 74.2% Target: 65% (Target Exceeded)	65%	65%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
253221: Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2022: 100.0% Target: 65% (Target Exceeded)	65%	65%	Maintain
214206: Maintain accreditation for ORA labs. (Outcome)	FY 2022: 13 labs Target: 13 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 2022: 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

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 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.

PROGRAM ACTIVITY DATA

Field Foods Program Activity Data (PAD)			
Field Foods Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC FOOD ESTABLISHMENT INSPECTIONS	***7,099***	***7,661***	***7,661***
Domestic Food Safety Program Inspections	4,523	Activities no longer planned to this level due to enactment of FSMA and alignment of resources into only high and low risk categories.	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	90		
Domestic Low Acid Canned Foods/ Acidified Foods Inspections	208		
Domestic Fish & Fishery Products (HACCP) Inspections	573		
Import (Seafood Program Including HACCP) Inspections	120		
Juice HACCP Inspection Program (HACCP)	111		
Interstate Travel Sanitation (ITS) Inspections	492		
Domestic Field Exams/Tests	*1,200*	2,082	2,082
Domestic Laboratory Samples Analyzed	*13,603*	15,164	15,164
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN FOOD ESTABLISHMENT INSPECTIONS [1]	***304***	***1,230***	***1,230***
All Foreign Inspections	*304*	1,230	1,230
TOTAL UNIQUE COUNT OF FDA FOODS ESTABLISHMENT INSPECTIONS	***7,403***	***8,890***	***8,890***
IMPORTS			
Import Field Exams/Tests[2]	*94,353*	140,673	140,673
Import Laboratory Samples Analyzed	*14,163*	17,609	17,609
Import Physical Exam Subtotal	**108,516**	**158,282**	**158,282**
Import Line Decisions	19,344,104	19,537,545	19,732,920
Percent of Import Lines Physically Examined	0.56%	0.81%	0.80%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT FOOD ESTABLISHMENT INSPECTIONS	***5,761***	***7,106***	***7,106***
State Contract Food Safety (Non HACCP) Inspections	4,952	6,263	6,263
State Contract Domestic Seafood HACCP Inspections	492	679	679
State Contract Juice HACCP	$31	$46	$46
State Contract LACF/Acidified Food Inspections	84	101	101
State Contract Foods Funding	$12,780,932	$12,908,741	$13,037,828
GRAND TOTAL FOOD ESTABLISHMENT INSPECTIONS	***13,164***	***15,997***	***15,997***

[1] The FY 2021 actual unique count of foreign inspections includes 77 OGPS inspections (57 for China, 2 for India, & 18 for Latin America).

[2] ORA is currently evaluating the calculations for future estimates.

[3] State partnership inspections have been removed from the PAD as they have been phased out. All state inspections are now accounted for under the "state contract" inspection category.

[4] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 53 – ORA Workload and Outputs 1/6

Field Human Drugs Program Activity Data (PAD)			
Field Human Drugs Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,064***	***1,432***	***1,432***
Pre-Approval Inspections (NDA)	66	70	70
Pre-Approval Inspections (ANDA)	60	80	80
Bioresearch Monitoring Program Inspections	420	571	571
Drug Processing (GMP) Program Inspections	398	540	540
Compressed Medical Gas Manufacturers Inspections	22	33	33
Adverse Drug Events Project Inspections	52	66	66
OTC Monograph Project and Health Fraud Project Inspections	8	15	15
Compounding Inspections[1]	76	110	110
Domestic Laboratory Samples Analyzed	933	970	970
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN HUMAN DRUG ESTABLISHMENT INSPECTIONS [2]	***400***	***962***	***962***
Foreign Pre-Approval Inspections (NDA) incl PEPFAR	75	92	92
Foreign Pre-Approval Inspections (ANDA) incl PEPFAR	96	158	158
Foreign Bioresearch Monitoring Program Inspections incl PEPFAR	128	231	231
Foreign Drug Processing (GMP) Program Inspections	127	531	531
Foreign Adverse Drug Events Project Inspections	2	5	5
TOTAL UNIQUE COUNT OF FDA HUMAN DRUG ESTABLISHMENT INSPECTIONS	***1,464***	***2,394***	***2,394***
IMPORTS			
Import Field Exams/Tests	5,196	7,140	7,140
Import Laboratory Samples Analyzed	1,078	885	885
Import Physical Exam Subtotal	**6,274**	**8,025**	**8,025**
Import Line Decisions	1,021,775	1,052,428	1,084,001
Percent of Import Lines Physically Examined	0.61%	0.76%	0.74%
GRAND TOTAL HUMAN DRUG ESTABLISHMENT INSPECTIONS [5]	***1,464***	***2,394***	***2,394***

[1] The number of compounding inspections includes inspections of compounders that are not registered with FDA as outsourcing facilities.

[2] The FY 2021 actual unique count of foreign inspections includes 34 OGPS inspections (25 for China, 9 for India, and 0 for Latin America).
[3] ORA is currently evaluating the calculations for future estimates.

[4] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.
[5] Count of "Third Party" Foreign Inspections 28 (not included in Overall counts above)

Figure 54 – ORA Workload and Outputs 2/6

Field Cosmetics Program Activity Data (PAD)			
Field Cosmetics Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***52***	***65***	***65***
Domestic Inspections	52	65	65
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA COSMETICS ESTABLISHMENT INSPECTIONS	***3***	***0***	***0***
Foreign Inspections	3	0	0
IMPORTS			
Import Field Exams/Tests[1]	3,869	4,883	4,883
Import Laboratory Samples Analyzed	286	290	290
Import Physical Exam Subtotal	**4,155**	**5,173**	**5,173**
Import Line Decisions	3,868,699	3,907,386	3,946,460
Import Line Decisions	0.11%	0.13%	0.13%
GRAND TOTAL COSMETICS ESTABLISHMENT INSPECTIONS	***55***	***65***	***65***

[1]ORA is currently evaluating the calculations for future estimates.

[2]In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 55 – ORA Workload and Outputs 3/6

Field Biologics Program Activity Data (PAD)			
Field Biologics Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,221***	***1,601***	***1,601***
Bioresearch Monitoring Program Inspections	152	107	107
Blood Bank Inspections	489	689	689
Source Plasma Inspections	160	206	206
Pre-License, Pre-Market Inspections	32	69	69
GMP Inspections	28	40	40
GMP (Device) Inspections	8	10	10
Human Tissue Inspections	375	517	517
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN BIOLOGICS ESTABLISHMENT INSPECTIONS	***41***	***59***	***59***
Bioresearch Monitoring Program Inspections	7	10	10
Foreign Human Tissue Inspections	0	1	1
Blood Bank Inspections	7	7	7
Pre-License, Pre-market Inspections	1	5	5
GMP Inspections (Biologics & Device)	23	33	33
TOTAL UNIQUE COUNT OF FDA BIOLOGIC ESTABLISHMENT INSPECTIONS	***1,262***	***1,660***	***1,660***
IMPORTS			
Import Field Exams/Tests	112	97	97
Import Line Decisions	64,884	138,929	140,318
Percent of Import Lines Physically Examined	0.17%	0.07%	0.07%
GRAND TOTAL BIOLOGICS ESTABLISHMENT INSPECTIONS	***1,262***	***1,660***	***1,660***

[1] ORA is currently evaluating the calculations for future estimates.

[2] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 56 – ORA Workload and Outputs 4/6

Field Animal Drugs & Foods Program Activity Data (PAD)									
Field Animal Drugs and Foods Program Workload and Outputs	**FY 2022 Estimate**			**FY 2023 Estimate**			**FY 2024 Estimate**		
	Total	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**	**Total**	**Animal Drugs**	**Feeds**
FDA WORK									
DOMESTIC INSPECTIONS									
UNIQUE COUNT OF FDA DOMESTIC ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS	***855***	***70***	***785***	***1,225***	***132***	***1,094***	***1,225***	***132***	***1,094***
Pre-Approval /BIMO Inspections	24	24	0	36	36	0	36	36	0
Drug Process and New ADF Program Inspections	44	44	0	94	94	0	94	94	0
BSE Inspections	227	0	227	476	0	476	476	0	476
Feed Contaminant Inspections	0	0	0	2	0	2	2	0	2
Illegal Residue Program Inspections	108	0	108	254	0	254	254	0	254
Feed Manufacturing Program Inspections	181	0	181	190	0	190	190	0	190
Domestic Laboratory Samples Analyzed	437	0	437	976	5	971	976	5	971
FOREIGN INSPECTIONS									
UNIQUE COUNT OF FDA FOREIGN ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS1	***21***	***12***	***9***	***62***	***45***	***17***	***62***	***45***	***17***
Foreign Pre-Approval/Bioresearch Monitoring Program Inspections	9	8	0	15	15	0	15	15	0
Foreign Drug Processing and New ADF Program Inspections	6	6	0	32	32	0	32	32	0
Foreign Feed Inspections	0	0	0	2	0	2	2	0	2
BSE Inspections	1	0	1	2	0	2	2	0	2
TOTAL UNIQUE COUNT OF FDA ANIMAL DRUGS AND FOODS ESTABLISHMENT INSPECTIONS	***876***	***82***	***794***	***1,287***	***176***	***1,111***	***1,287***	***176***	***1,111***
IMPORTS									
Import Field Exams/Tests	2,870	791	2,079	3,078	827	2,252	3,078	827	2,252
Import Laboratory Samples Analyzed	536	0	536	799	0	798	799	0	798
Import Physical Exam Subtotal	**3,406**	**791**	**2,615**	**3,877**	**827**	**3,050**	**3,877**	**827**	**3,050**
Import Line Decisions	572,292	81,003	491,289	578,015	81,813	496,202	583,795	82,631	501,164
Percent of Import Lines Physically Examined	0.60%	0.98%	0.53%	0.67%	1.01%	0.61%	0.66%	1.00%	0.61%
STATE WORK									
UNIQUE COUNT OF STATE CONTRACT ANIMAL FEEDS ESTABLISHMENT INSPECTIONS	***987***	***0***	***987***	***2,055***	***0***	***2,055***	***2,055***	***0***	***2,055***
State Contract Inspections: BSE	433	0	435	1,389	0	1,389	1,389	0	1,389
State Contract Inspections: Feed Manufacturers	266	0	266	447	0	447	447	0	447
State Contract Inspections: Illegal Tissue Residue	$2,583,086	0	$2,583,086	$2,608,917	0	$2,608,917	$2,635,006	0	$2,635,006
	1,863	82	1,781	3,342	176	3,166	3,342	176	3,166
State Contract Animal Feeds Funding	$2,716,170	0	$2,716,170	$2,743,331	0	$2,743,331	$2,770,765	0	$2,770,765
State Contract Tissue Residue Funding	$0	0	$0	$0	0	$0	$0	0	$0
Total State Funding	**$2,716,170**	**$0**	**$2,716,170**	**$2,743,331**	**$0**	**$2,743,331**	**$2,770,765**	**$0**	**$2,770,765**
GRAND TOTAL ANIMAL DRUGS AND FEEDS ESTABLISHMENT INSPECTIONS	***2,858***	***182***	***2,676***	***5,032***	***283***	***4,749***	***5,032***	***283***	***4,749***

[1] The FY 2021 actual unique count of foreign inspections includes 4 OGPS inspections (4 for China).

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number is expected to decrease in the future until there are no planned State Partnership inspections.

[3] The State cooperative agreement BSE inspections that are funded by the FDA are now being obligated via formal contract funding vehicles and this number along with the funding for these inspections are expected to decrease in the future until there are no planned State Cooperative Agreement BSE inspections.

[4] Tissue residue funding has ended in FY18 and state contract illegal tissue residue inspections are no longer being conducted.

[5] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

Figure 57 – ORA Workload and Outputs 5/6

Field Devices and Radiological Health Program Activity Data (PAD)			
Field Devices and Radiological Health Program Workload and Outputs	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
FDA WORK			
DOMESTIC INSPECTIONS			
UNIQUE COUNT OF FDA DOMESTIC DEVICES ESTABLISHMENT INSPECTIONS	***1,984***	***2,439***	***2,439***
Bioresearch Monitoring Program Inspections	215	300	300
Pre-Market Inspections	34	60	60
Post-Market Audit Inspections	20	35	35
GMP Inspections	1,062	1,300	1,300
Inspections (MQSA) FDA Domestic (non-VHA and VHA)	642	750	750
Domestic Radiological Health Inspections	59	65	65
Domestic Field Exams/Tests	32	45	45
Domestic Laboratory Samples Analyzed	123	170	170
FOREIGN INSPECTIONS			
UNIQUE COUNT OF FDA FOREIGN DEVICES ESTABLISHMENT INSPECTIONS [1]	***65***	***620***	***620***
Foreign Bioresearch Monitoring Inspections	3	14	14
Foreign Pre-Market Inspections	4	30	30
Foreign Post-Market Audit Inspections	5	20	20
Foreign GMP Inspections	41	550	550
Foreign MQSA Inspections	1	14	14
Foreign Radiological Health Inspections	20	50	50
TOTAL UNIQUE COUNT OF FDA DEVICE ESTABLISHMENT INSPECTIONS	***2,049***	***3,058***	***3,058***
Import Field Exams/Tests	18,563	22,000	22,000
Import Laboratory Samples Analyzed	503	670	670
Import Physical Exam Subtotal	**19,066**	**22,670**	**22,670**
Import Line Decisions	25,205,483	25,961,648	26,740,497
Percent of Import Lines Physically Examined	0.08%	0.09%	0.08%
STATE WORK			
UNIQUE COUNT OF STATE CONTRACT DEVICES ESTABLISHMENT INSPECTIONS [2]	***7,065***	***7,090***	***7,090***
Inspections (MQSA) by State Contract	7,029	7,050	7,050
GMP Inspections by State Contract	36	40	40
State Contract Devices Funding	$124,724	$127,218	$129,763
State Contract Mammography Funding	$10,590,612	$10,696,518	$10,803,483
Total State Funding	**$10,715,336**	**$10,823,737**	**$10,933,246**
GRAND TOTAL DEVICES ESTABLISHMENT INSPECTIONS	***9,114***	***10,148***	***10,148***

[1] The FY 2021 actual unique count of foreign inspections includes 6 OGPS inspections (6 for China)

[2] The State inspections that are funded by the FDA are now being obligated via formal contract funding vehicles.

3 Domestic MQSA Non-VHA and VHA Inpsections have been combined into one output line.

[4] ORA is currently evaluating the calculations for future estimates.

[5] In accordance with national guidelines due to the COVID-19 pandemic restrictions, ORA scaled back foreign and domestic inspection work and target its resources on the highest- risk facilities and industries during FY20 and FY21. ORA will continue to monitor progress throughout FY22.

[6] Count of "Third Party" Device Inspections (not included in Overall counts above) Foreign 4 and Domestic 3

Figure 58 – ORA Workload and Outputs 6/6

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 Americans from tobacco-related death and disease by regulating the manufacture, distribution, and marketing of tobacco products, and by educating the public, including youth, about the risks of tobacco product use.

FDA executes regulatory and public health responsibilities in program areas that support the following objectives:

- Reducing initiation of tobacco product use
- Decreasing the harms of tobacco products
- Encouraging cessation among tobacco product users

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 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Tobacco	**752,921**	**765,697**	**679,944**	**677,165**	**779,965**	**102,800**
Center	732,476	746,810	652,459	654,671	748,687	94,016
Field	20,444	18,887	27,485	22,494	31,278	8,784
FTE	**1,040**	**1,228**	**1,287**	**1,303**	**1,312**	**9**

Figure 59 - CTP Funding History Table

The FY 2024 President's Budget is $779,965,000, all of which is user fees. The user fees amount is $100,000,000 above the FY 2024 level authorized in the Tobacco Control Act less the amounts for GSA Rent, FDA Headquarters, FDA White Oak Campus, and Other Rent and Rent Related, which are shown in their own sections of the budget request. This amount is $102,800,000 above the FY 2023 Enacted Budget. The Center for Tobacco Products amount in this request is $748,687,000.

USER FEES

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, and the effectiveness of the tobacco program will continue to be degraded 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 using tobacco-derived nicotine and those using non-tobacco nicotine (NTN), which includes synthetic nicotine. Therefore, FDA requests an additional $100 million and requests

authority to include manufacturers and importers of all deemed products among the tobacco product classes for which FDA assesses tobacco user fees. This additional funding will 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.

To ensure that resources keep up with new tobacco products, the proposal would also index future collections to inflation. 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.

In FY 2024, CTP will continue to take action to protect American families by focusing on the Center's six strategic priorities:

- Comprehensive FDA Nicotine Regulatory Policy
- Premarket and Postmarket Controls: Regulations and Product Reviews
- Product Standards
- Public Education
- Compliance and Enforcement
- Investing in Human Capital

Comprehensive FDA Nicotine Regulatory Policy

Almost 90 percent of adult smokers start smoking by the age of 18,[86] and more than 1,000 youth aged 12 to 17 smoke their first cigarette every day in the United States.[87] FDA's comprehensive plan serves as a multi-year roadmap to protect youth and significantly reduce tobacco-related disease and death. FDA regulates a broad range of nicotine-delivering products, from cigarettes to medicinal nicotine gum and patch. FDA is pursuing an integrated, agency-wide policy on nicotine-containing products that is public health based and recognizes the continuum of risk among such products.

FDA will continue to implement the comprehensive plan by:

- Implementing the Youth Tobacco Prevention Plan to prevent access to – and use of – tobacco products, particularly e-cigarettes by children and teens
- Conducting science-based review of tobacco products
- Working on foundational rules such as proposed rules on tobacco product manufacturing practices and Modified Risk Tobacco Product (MRTP) Applications
- Working toward issuing final product standards to prohibit menthol as a characterizing flavor in combusted cigarettes and prohibit all characterizing flavors (including menthol) in cigars
- Working toward developing a proposed product standard that would establish a maximum nicotine level in cigarettes and certain finished tobacco products.

[86] U.S. Department of Health and Human Services (USDHHS). The Health Consequences of Smoking - 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health; 2014. Retrieved from https://www.ncbi.nlm.nih.gov/books/NBK179276/

[87] https://www.samhsa.gov/data/release/2020-national-survey-drug-use-and-health-nsduh-releases

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 including new guidances for industry and potential educational campaigns to correct misperceptions related to nicotine and addiction
- Exploring options for expanding pharmacotherapies and other means for treating nicotine addiction and promoting cessation.

Premarket and Postmarket Controls: Regulations and Product Reviews

FDA serves as a critical public health gatekeeper between tobacco product manufacturers and consumers by performing a scientific review before new tobacco products are commercially marketed and sold. Manufacturers are required to obtain FDA authorization before marketing new[88] tobacco products:

- By demonstrating they are appropriate for protection of the public health, or
- By demonstrating substantial equivalence[89] to a valid predicate tobacco product, or
- By demonstrating they are exempt from the requirements of substantial equivalence.

Work continues on foundational rules such as a proposed rule that would address tobacco product manufacturing practices and a proposed rule that would establish content and format requirements for MRTP Applications.

In addition to developing rules and guidances, CTP also regularly evaluates the application review process to identify areas where process improvements could enhance CTP work efficiencies. Further, CTP is hiring additional scientific and regulatory staff to review product applications.

Product Standards

Section 907 of the Federal Food, Drug, and Cosmetic Act (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. Based on this authority, in April 2022, FDA issued proposed product standards to prohibit menthol as a characterizing flavor in combusted cigarettes and to prohibit all characterizing flavors (including menthol) in cigars. The public comment period on the proposals closed on August 2, 2022, and FDA is reviewing and considering the comments submitted.

[88] 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.

[89] A pathway to market for new tobacco products where the applicant has to demonstrate that the characteristics of the new tobacco product(s) are the same as the corresponding predicate product(s) (which is a product that was commercially marketed in the United States as of February 15, 2007 (other than for test markets), or a product previously found to be substantially equivalent) or the characteristics are different, but the new product does not raise different questions of public health.

Also, the Administration recently published plans for future potential regulatory actions that include 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.

Public Education

FDA maximizes impact on public health by focusing public education efforts on at-risk audiences such as youth who are already experimenting with tobacco or are susceptible to use.

Campaign messaging and outreach tactics for different product types, including e-cigarettes, cigarettes and little cigars and cigarillos, will continue to target at-risk populations and be informed by findings from formative research, market intelligence perception surveillance, results of outcome evaluations and real-time tracking efforts, as well as changes in youth tobacco use trends.

To maximize the impact on public health and address the high usage rates, FDA will continue prioritizing e-cigarette prevention campaigns for youth.

FDA will also continue to:

- Conduct research and evaluation to design and implement campaigns that effectively educate at-risk populations, especially young people, about the dangers of using tobacco products.
- Develop and disseminate education materials for adults that 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[90], which provides free youth tobacco prevention and adult cessation materials and resources to public health stakeholders and local organizations.
- Expand the Vaping Prevention and Education Resource Center[91] by developing new and innovative resources for middle and high school educators and parents.
- Raise tobacco retailers' awareness and understanding of FDA tobacco regulations and requirements to encourage voluntary compliance through the "This is Our Watch"[92] Retailer Education initiative.

FDA will also initiate formative research to assess the impact of messaging on the continuum of risk among adult smokers, as well as unintended effects among non-target populations, including youth.

Compliance and Enforcement

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 focus on actions that are supported by evidence of violations of the law. FDA will continue to take vigorous compliance and enforcement actions aimed at unauthorized e-cigarette

[90] https://digitalmedia.hhs.gov/tobacco/

[91] https://digitalmedia.hhs.gov/tobacco/educator_hub

[92] https://www.fda.gov/tobacco-products/retail-sales-tobacco-products/our-watch

products that remain on the market and ensuring that all tobacco products are not being marketed and/or sold to underage persons.

Continued planned activities include:

- Investigating whether manufacturers may be manufacturing and/or marketing new ENDS products, including those containing NTN, that have not gone through premarket review or received a negative marketing order from the agency
- Prioritizing the enforcement of 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
- Closely 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 sales, distribution, marketing, promotion, advertising, and labeling requirements, including for products containing NTN, by issuing Civil Money Penalties (CMPs), No-Tobacco-Sale Orders (NTSOs) or other actions such as injunctions, seizures or criminal prosecution
- Referring potential criminal activity to FDA's Office of Criminal Investigations
- Informing small businesses of existing guidances, regulations, and submission pathways through publications and online webinars and answering questions from regulated industry.

Investing in Human Capital

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. FDA is committed to diversity, equity, inclusion, and accessibility (DEIA) to cultivate an engaged workforce that reflects the country it serves. DEIA are core values and CTP is making significant efforts to uphold these values. CTP established and will continue to support the DEIA Council, an employee led initiative to bring diverse viewpoints forward. CTP also updated the Center's DEIA Strategic Plan, which included significant input from the Council. CTP offers DEIA trainings and prioritizes recruitment of highly qualified diverse candidates through attendance at career fairs and sharing job opportunities with Minority Serving Institutions (MSI) for external announcements. Furthermore, FDA has recently announced the addition of the position of Senior Advisor for Health Equity to CTP's leadership team to help lead the Center's efforts to address tobacco-related health disparities.

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, supporting the Youth Tobacco Prevention Plan, a key component of the agency's Comprehensive Plan for Tobacco and Nicotine Regulation.
- 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.

The Reagan-Udall Foundation, an independent partner organization for the agency, conducted an evaluation of tobacco program operations. FDA will continue utilizing the report findings to implement recommended changes, as appropriate, moving forward.

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, making decisions on whether new tobacco products and claims can be marketed—including the review and evaluation of applications and claims before the new products are allowed on the market, and enforcing the law when violations are found.

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.

Additionally, an important new federal law went into effect on April 14, 2022[93] clarifying FDA's authority to regulate tobacco products containing NTN – that is, nicotine from any source, such as synthetic nicotine. As of April 14, 2022, manufacturers, distributors, importers, and retailers of tobacco products containing NTN must ensure compliance with applicable requirements under the FD&C Act resulting from this law, including premarket review.

On April 28, 2022, FDA announced[94] proposed product standards to prohibit menthol as a characterizing flavor in combusted cigarettes[95] and prohibit all characterizing flavors (other than tobacco) in cigars.[96] These proposed product standards are based on clear science and evidence establishing the addictiveness and harm of these products and build on the statutory ban of other flavored cigarettes in 2009. These actions have the potential to significantly reduce youth initiation, increase the chances of smoking cessation among current adult smokers, and address health disparities experienced by underserved communities and at risk populations, such as youth and young adults, some racial and ethnic populations, those with lower household income and educational attainment, and individuals who identify as lesbian, gay, bisexual, transgender, or queer (LGBTQ+), all of whom are more likely to use tobacco products.

Characterizing flavors in tobacco products, including menthol, enhance taste and make them easier to use. Menthol in particular masks the harshness and irritation of tobacco smoke and reduces initial aversive responses to smoking, particularly for young people. As referenced in the proposed rule[97], menthol also interacts with nicotine in the brain to enhance nicotine's addictive effects. The combination of menthol's flavor, sensory effects, and interaction with nicotine in the brain increases the likelihood that youth who start using menthol cigarettes will progress to regular use. Menthol also makes it more difficult for people to quit smoking.

After the 2009 statutory ban on flavors in cigarettes other than menthol, use of flavored cigars increased, suggesting that the public health goals of the flavored cigarette ban may have been undermined by continued availability of these flavored cigars. Flavored little cigars and cigarillos are combusted tobacco products that can closely resemble cigarettes, pose many of the same public health risks, and are disproportionately popular among certain racial/ethnic minority youth and other populations.

Additional information about the impact of menthol in combusted cigarettes and flavors in cigars and the impacts these products have on society and health equity can be found in the FDA Fact Sheet at https://www.fda.gov/media/158015/download.

On June 21, 2022, the Spring 2022 Unified Agenda of Regulatory and Deregulatory actions was published and included FDA's plans to develop a proposed product standard[98] that would establish a maximum nicotine level to reduce the addictiveness of cigarettes and certain other

[93] https://www.fda.gov/tobacco-products/ctp-newsroom/requirements-products-made-non-tobacco-nicotine-take-effect-april-14

[94] https://www.fda.gov/news-events/press-announcements/fda-proposes-rules-prohibiting-menthol-cigarettes-and-flavored-cigars-prevent-youth-initiation

[95] https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes

[96] https://www.federalregister.gov/documents/2022/05/04/2022-08993/tobacco-product-standard-for-characterizing-flavors-in-cigars

[97] https://www.federalregister.gov/documents/2022/05/04/2022-08994/tobacco-product-standard-for-menthol-in-cigarettes

[98] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202204&RIN=0910-AI76

combusted tobacco products.[99] The goals of the potential rule would be to reduce youth use, addiction, and death. 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.[100]

While nicotine is not what makes smoking cigarettes toxic, it's the ingredient that makes it very hard to quit smoking. 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 make those products minimally 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 help more currently addicted smokers to quit.

Product Review and Evaluation

FDA's authority to regulate tobacco products includes premarket review of new tobacco products to determine if their marketing is appropriate for the protection of the public health, if they are substantially equivalent to a valid predicate tobacco product, or if they are exempt from the requirements of substantial equivalence.

New 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)

PMTA and Substantial Equivalence

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. From October 1, 2021, to November 30, 2022, CTP issued Marketing Granted Orders (MGOs) under the PMTA pathway for 23 ENDS and four oral tobacco products.[101] These MGOs include marketing restrictions on the company to greatly reduce the potential for youth exposure to tobacco advertising for the products. The FDA may suspend or withdraw an MGO issued under the PMTA pathway for a variety of reasons if the agency determines the continued marketing of a product is no longer APPH, such as if there is a notable increase in youth initiation.

On October 26, 2022, CTP announced issuance of Marketing Denial Orders[102] for several menthol flavored e-cigarette products. These are the first menthol e-cigarette products to receive

[99] https://www.fda.gov/news-events/press-announcements/fda-announces-plans-proposed-rule-reduce-addictiveness-cigarettes-and-other-combusted-tobacco

[100] https://doi.org/10.1016/j.amepre.2022.04.032

[101] https://www.fda.gov/tobacco-products/premarket-tobacco-product-applications/premarket-tobacco-product-marketing-granted-orders

[102] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-products-marketing-orders#Marketing%20Denial

a marketing decision based on full scientific review from the FDA. As a result, these products can no longer be marketed or distributed in the United States.

Under the SE pathway, manufacturers may submit SE Reports[103] to seek FDA authorization to legally market a new tobacco product. 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 (as opposed to provisional SE Reports which are applications for new tobacco products that meet the following criteria: (1) 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 the new product does not raise different questions of public health. A valid predicate tobacco product is one that was commercially marketed in the United States – other than in a test market – as of February 15, 2007, or a product previously found to be substantially equivalent by FDA.

FDA reviews these SE Reports to determine if the new tobacco product is substantially equivalent and is in compliance with the requirements of the law. If both criteria are met, FDA issues an order permitting the product to be legally marketed in the United States.

Modified Risk Tobacco Products

Before marketing a tobacco product to reduce harm or the risk of tobacco-related disease, manufacturers must submit a MRTP Application and receive an FDA order authorizing that the product reduces harm or the risk of tobacco-related disease. 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. From October 1, 2021, to November 30, 2022, CTP issued Modified Risk Granted Orders for two types of very low nicotine cigarettes and one heated tobacco product (HTP), which authorizes the products to be marketed with specific claims related to reduced exposure.[104] The same PMTA authorization marketing restrictions apply to these tobacco products. These restrictions are intended to reduce the potential for youth exposure to tobacco advertising for the products. The FDA may withdraw the initial and any subsequent exposure modification orders if the agency determines that, among other things, the orders are no longer expected to benefit the health of the population as a whole.

Status of Submitted Applications

The following table summarizes the status of tobacco product applications received, including SE Exemption Requests, Regular SE Reports, PMTAs and MRTP Applications through October 31, 2022.

[103] https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/substantial-equivalence

[104] https://www.fda.gov/tobacco-products/advertising-and-promotion/modified-risk-granted-orders

FDA posts expanded data on its Tobacco Product Application Metrics & Reporting webpage which can be found here: https://www.fda.gov/tobacco-products/market-and-distribute-tobacco-product/tobacco-product-applications-metrics-reporting.

Tobacco Product Applications Received, Open, Pending, and Closed by Product Class

Application Status	Product Class[105]	Cumulative through 10/31/2022[106]				
		Exemption Requests	Regular SE Reports	Provisional SE Reports	Premarket Tobacco Product Applications	Modified Risk Tobacco Product Applications
Received	Cigar	372	3,457	0	15	0
	Cigarette	1,505	1,807	2,390	5	18
	ENDS(VAPES)	0	2	18	9,072,569	14
	HTP	2	6	2	21	0
	Other	0	57	0	1,646	0
	Pipe	6	1,822	0	12	0
	Roll-Your-Own	27	1,311	646	4	0
	Smokeless	65	550	589	32	19
	Waterpipe	1,960	2,894	0	75	0
	Total	3,937	11,906	3,645	9,074,379	51
Open	Cigar	118	2,990	0	10	0
	Cigarette	521	428	335	0	3
	ENDS(VAPES)	0	0	0	327,957	0
	HTP	0	0	0	13	0
	Other	0	55	0	1,089	0
	Pipe	6	1,282	0	12	0
	Roll-Your-Own	0	252	13	0	0
	Smokeless	7	132	76	18	7
	Waterpipe	517	895	0	0	0
	Total	1,169	6,034	424	329,099	10
Closed[107]	Cigar	254	467	0	5	0
	Cigarette	984	1,379	2,055	5	15

[105] Other includes tobacco products that are not defined (e.g., nicotine gel, dissolvable products from extracts, tobacco-derived nicotine discs) and products not under CTP jurisdiction.

[106] These include NTN tobacco products submitted by 5/14/22.

[107] Closed includes refuse-to-accept, refuse-to-file, remove from review, issuance of an order, environmental information request, withdrawn, or closure due to administrative issues.

Application Status	Product Class[105]	Cumulative through 10/31/2022[106]				
		Exemption Requests	Regular SE Reports	Provisional SE Reports	Premarket Tobacco Product Applications	Modified Risk Tobacco Product Applications
	ENDS(VAPES)	0	2	18	8,744,612	14
	HTP	2	6	2	8	0
	Other	0	2	0	557	0
	Pipe	0	540	0	0	0
	Roll-Your-Own	27	1,059	633	4	0
	Smokeless	58	418	513	14	12
	Waterpipe	1,443	1,999	0	75	0
	Total	2,768	5,872	3,221	8,745,280	41

Research

FDA invests in research to inform regulatory actions by addressing scientific knowledge gaps and enhancing scientific understanding. In FY 2022, FDA invested more than $160 million in scientific research with a focus 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. Research priorities address the following Scientific Domains[108]: Product Composition and Design; Toxicity; Addiction; Health Effects; Behavior; Communications; Marketing Influences; and Impact Analysis.

In addition to conducting independent research to support regulatory science, CTP partners with several other FDA Centers including NCTR and 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 2022, FDA funded more than 150 research projects via NIH TRSP. These research projects include grants which will address important FDA research priorities.[109]

A key component of the CTP – NIH TRSP collaboration includes funding nine Tobacco Centers of Regulatory Science (TCORS). The objective of TCORS is to conduct multidisciplinary

[108] https://www.fda.gov/tobacco-products/research/research-priorities

[109] https://prevention.nih.gov/tobacco-regulatory-research

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 are raised in today's rapidly evolving tobacco marketplace. FDA expects to award a new round of eight TCORS through NIH TRSP in FY 2023.

A new CTP-funded research initiative with NIH TRSP was published in FY 2022. The Center for Rapid Surveillance of Tobacco (CRST) is designed to assess changes in use behaviors, product marketing, and the marketplace to better understand the rapidly evolving tobacco landscape in the United States. The CRST will support time-sensitive data acquisition strategies, data harmonization, data synthesis and analysis, and reporting activities on emerging and current tobacco use. Applications are currently under review. FDA expects to make one award through NIH TRSP in FY 2023.

Population Assessment of Tobacco and Health (PATH) Study

FDA funds the PATH Study[110] via NIH's National Institute on Drug Abuse (NIDA), with 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 questionnaire data[111] are made available to researchers and the public.

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), the Pregnancy Risk Assessment Monitoring System (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 survey data allows FDA to monitor youth awareness of, susceptibility to, experimentation with, and use of, a wide range of tobacco products. Findings from the 2022 NYTS (conducted January 18-May 31, 2022) indicated that an estimated 2.55 million U.S. middle and high school students reported currently using e-cigarettes in 2022, the majority of which reported flavored e-cigarette use (84.9 percent).[112]

[110] https://www.fda.gov/tobacco-products/research/fda-and-nih-study-population-assessment-tobacco-and-health

[111] https://www.icpsr.umich.edu/web/NAHDAP/series/606

[112] Cooper M, Park-Lee E, Ren C, Cornelius M, Jamal A, Cullen KA. Notes from the Field: E-cigarette Use Among Middle and High School Students — United States, 2022. MMWR Morb Mortal Wkly Rep 2022;71:1283–1285. DOI: http://dx.doi.org/10.15585/mmwr.mm7140a3.

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 Marketing Denial Order (MDO) and those for which no application was submitted.

- From January 2021 through October 31, 2022, the Agency issued more than 300 warning letters to firms that did not submit timely premarket applications for tobacco-derived nicotine (TDN) products (over 120 were issued in FY22).
- Through October 31, 2022, FDA also issued warning letters to more than 135 companies for continuing to unlawfully market TDN ENDS products that are the subject of a negative decision, such as an MDO, a Refuse to Accept (RTA) letter, or a Refuse to File (RTF) letter (over 130 of were issued in FY22).
- On October 18, 2022, the U.S. Department of Justice, 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.

Additionally, from October 1, 2021, through October 31, 2022, as part of the Youth Tobacco Prevention Plan and consistent with FDA's policy to prioritize the enforcement of certain e-cigarettes and other deemed products on the market, the agency has taken the following actions to stop youth use of, and access to, ENDS products:

- Refused admission into the U.S. of over 160 shipments of tobacco products, including disposable ENDS, for violations of the FD&C Act.
- Issued more than 60 warning letters to manufacturers for marketing NTN products without the required premarket authorization and issued more than 380 warning letters to retailers for illegally selling NTN products to underage purchasers.

Tobacco Retailer Inspection Program

As of October 31, 2022, FDA has contracts for tobacco retailer compliance check inspections in 56 states and 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 most 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. A searchable database of all retailer inspections and all enforcement actions that have resulted from those inspections is available at: https://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

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). FDA also facilitates inspections at vape shops using contracted inspectors. Since the inception of the Tobacco Program's manufacturer inspection

activities through October 31, 2022, CTP has overseen the completion of more than 4,000 inspections of vape shops to verify whether they were engaged in manufacturing activities, and ORA has completed over 1,500 routine biennial inspections of tobacco product manufacturers, a small percentage of which were Remote Regulatory Assessments (RRAs). Please see the ORA Chapter for more information about ORA's tobacco operations.

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, June 22, 2009, through October 31, 2022, FDA has issued over 1,100 warning letters as a result of its internet and publication surveillance activities. This includes issuance of over 130 warning letters in FY 2022. 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 a proven, evidence-based component of comprehensive tobacco control efforts. Under the Tobacco Control Act, FDA has the authority to educate the public about the dangers of using tobacco products and has implemented multiple public education efforts 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 in all its forms. FDA implements multi-year outcome evaluation with a longitudinal cohort design to evaluate the impact of exposure to "The Real Cost" cigarettes and e-cigarettes prevention campaigns on changes in beliefs about the products in a nationally representative sample of youth.

The Real Cost – Cigarette Prevention

In February 2014, FDA launched its first national youth smoking prevention campaign and the campaign brand, "The Real Cost." The campaign is designed to prevent youth who were open to smoking cigarettes from doing so and to reduce the number of youths who moved from experimenting with smoking cigarettes to regular use.

Over the past eight years, the campaign has generated over 22 billion teen views of ad messages. Across social media platforms, the campaign has engaged teens resulting in more than 20 million likes, over 1 million shares, and over 410,000 comments.

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 youth audiences that have a higher prevalence and risk of smoking. FDA plans to launch new cigarette smoking prevention advertising in 2023.

The Real Cost – ENDS Prevention

Due to the success of the initial "The Real Cost" campaign and increasing rates of e-cigarette use, FDA modified and expanded the campaign to e-cigarettes. FDA's award-winning youth e-cigarette prevention campaign, "The Real Cost," aims to prevent the nearly 10.7 million youth aged 12-17 who are open to using e-cigarettes from trying them and to reduce the number of youth who move from experimenting with e-cigarettes to regular use.

Since launching in 2018, the campaign has shown positive results for effective reach and engagement. The campaign's advertising has reached up to 90 percent of all teenagers nationwide and has generated over 21 billion ad views and achieved high levels of online engagement. Across social media platforms, the campaign has engaged teen audiences resulting in more than 7.1 million likes, over 520,000 shares, and over 120,000 comments.

The latest wave of outcome evaluation results assessing the impact of "The Real Cost" youth e-cigarette prevention campaign is promising, indicating that more exposure to advertising increased population-level shifts in several negative beliefs about e-cigarettes among youth. In addition, recent outcome evaluation data collected between August and October 2021 showed that approximately 73 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.

FDA also partners with the NCI's Smokefree.gov initiative to provide youth with resources for quitting e-cigarettes. Newer resources and information on Teen.smokefree.gov, launched in July 2019, are designed for youth by cessation experts. "The Real Cost" connects youth to these resources on social media and various digital platforms.

Next Legends – ENDS Prevention

In June 2022, FDA launched "Next Legends" – an e-cigarette prevention campaign that aims to educate American Indian and Alaska Native (AI/AN) youth, ages 12-17, about the harms of vaping. Native youth are more susceptible to tobacco use than their non-Native peers, and they demonstrate disproportionately high experimentation with, and current use of, e-cigarettes.

The campaign uses unique branding and tailored messaging that is specifically designed to educate AI/AN youth on the harmful effects of vaping and was built on extensive qualitative research that was conducted in partnership with tribal leaders and AI/AN communities.

"Next Legends" is primarily a digital-based effort designed to reach Native teens on the platforms they commonly use, such as YouTube, Twitch, TikTok, and Instagram. In addition to the campaign's digital video and social media presence, out-of-home billboards, radio, and TV (Alaska) will also be used to help extend the message to AI/AN communities.

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. Tobacco-related health disparities are experienced by communities including, but not limited to, certain racial and ethnic populations, low-income populations, and LGBTQ+ individuals. To address tobacco-related health disparities, FDA uses evidence-based approaches in our public educational efforts; takes specific compliance and enforcement actions; recommends research studies include, where appropriate to the research question, populations of special relevance; and takes other actions to reduce health disparities and promote health equity.

Toward that end, FDA is working to issue tobacco product standards to prohibit menthol as a characterizing flavor in combusted cigarettes and prohibit all characterizing flavors (other than tobacco) in cigars, which will address longstanding health disparities related to smoking menthol cigarettes and flavored cigar products. In the U.S., it is estimated that there are nearly 17.5 million current smokers of menthol cigarettes, of whom nearly 40 percent smoke menthol cigarettes. But use of menthol cigarettes among smokers is not uniform; most notably, of Black smokers, nearly 85 percent smoke menthol cigarettes, compared to 30 percent of non-Hispanic

White smokers. Use of menthol cigarettes is also disproportionally higher among non-Hispanic Native Hawaiian and Pacific Islander smokers, Hispanic smokers, and sexual and gender minorities. And the difference in rates of use translates to disparities in rates of disease and death. For example, disproportionately high rates of tobacco-related illnesses and disease occur in Black communities compared to non-Hispanic White communities. Thus, while the rule would apply equally to all users of menthol cigarettes—including 9.3 million non-Hispanic White smokers—its effects would provide proportionately greater benefits to Black smokers and other populations with greater burden of use. Published modeling studies have estimated that if menthol cigarettes were no longer available, between 92,000 to 238,000 deaths among African Americans would be avoided over the course of 40 years.

FDA is also engaging in targeted education campaigns focused on at-risk populations such as the "Next Legends" campaign. FDA's data collection efforts also are being continually updated to include necessary data to assess disparities to help FDA promote health equity. For example, the PATH Study is using a health equity framework to guide the study methodology (e.g., sample design and development of interview questions) to ensure it provides data for researchers and the public to examine health disparities and inequities. The PATH Study also identifies main research questions that address health disparities and inequities related to tobacco use to prioritize for analysis and dissemination. Additionally, the 2022 NYTS conducted an oversample of AI/AN and Asian students. A recently published report[113] using the 2022 NYTS data presented estimates of Asian, AI/AN, Native Hawaiian or Other Pacific Islander, and multiracial population groups, allowing measurement of disparities in tobacco product use affecting these groups.

Reducing tobacco-related health disparities has been a foundational component of CTP's policies and programs as part of the Center's mission to protect and advance public health by helping to reduce harm from tobacco products. FDA has an opportunity to prioritize health equity and recently announced the addition of the position of Senior Advisor for Health Equity to CTP's leadership team to help lead the Center's work in this area.

[113] https://www.cdc.gov/mmwr/volumes/71/wr/mm7145a1.htm

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
280005: Total number of compliance check inspections of retail establishments in States under contract. (Outcome)	FY 2022: 93,065 Target: 75,000 (Target Exceeded)	90,000	110,000	+20,000
280010: Number of closed applications and deficiency letters for Premarket Tobacco Product Applications (PMTA). (Output)	FY 2022: 1,023,440 (historical actuals/baseline data)	600	660	+60
280011: Number of closed applications and deficiency letters for Substantial Equivalence (SE) Reports. (Output)	FY 2022: 516 (historical actuals/baseline data)	500	550	+50
280012: Number of closed applications and deficiency letters for Exemption from Substantial Equivalence Requests (EX REQ). (Output)	FY 2022: 820 (historical actuals/baseline data)	300	330	+30
280007: Educate at-risk youth (12-17 year olds) about the harmful effects of tobacco use. (Output)	FY 2022: Reached 75% of general market at risk 12-17 year olds with campaign messaging (Target Met)	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	Reach 75% of 12-17 year olds with campaign messaging within 1 year.	Maintain

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. Prior to FY 2020, FDA consistently conducted well over 100,000 inspections each fiscal year. In response to the COVID-19 pandemic, a partial stop work order for retailer inspections was put in place from March through September 2020. In FY 2023 and FY 2024, FDA expects jurisdictions and private entities to continue to contract with FDA and for inspections to return to pre-pandemic levels.

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 Letter (MGO); Marketing Denial Order Letter

(MDO). The measure also includes closure of a review cycle through issuance of a Deficiency Letter (DL). Generally, Deficiency letters may be issued during the substantive scientific review phase and list additional information that FDA needs to complete its scientific review. As an example, FDA has sent a Deficiency letter to an applicant to seek clarification of previously provided information, and to request additional analysis/data from a conducted study. 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 deadlines for ENDS and other new tobacco products. In FY 2022, CTP received close to one million due to requirements from the Consolidated Appropriations Act which provided FDA the authority to regulate tobacco products that contain non-tobacco sources of nicotine (e.g., synthetic nicotine). During this time, CTP was able to close over one million PMTAs through a focused review of flavored ENDS and data around youth initiation. In many instances, applications ultimately received an MDO due to lack of scientific information demonstrating a benefit to adult smokers that outweighs the increased youth risk related to tobacco-flavored ENDS. This review approach is still available to CTP, but in a far reduced capacity for the thousands of PMTA and SE applications that were received after the application deadline and are still awaiting substantive review–and for applications that will be submitted in the future–as these applications are more complete and require significantly more time to review. Therefore, while CTP's FY 2023 and FY 2024 targets are a significant reduction from our FY 2022 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 2024 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 Letter (SE); Not Substantially Equivalent Letter (NSE).The measure also includes closure of a review cycle through issuance of a Deficiency Letter (DL). Generally, Deficiency letters may be issued during the substantive scientific review phase and list additional information that FDA needs to complete its scientific review. As an example, FDA has sent a Deficiency letter to an applicant to seek clarification of previously provided information, and to request additional analysis/data from a conducted study. While CTP is strategically reallocating resources from this pathway to support the PMTA pathway, our targets are expected to increase through FY 2024 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 Letter (EX); Not Exempt Letter (NEX). The measure also includes closure of a review cycle through issuance of a Deficiency Letter (DL). Generally, Deficiency letters may be issued during the substantive scientific review phase and list additional information that FDA needs to complete its scientific review. As an example, FDA has sent a Deficiency letter to an applicant to seek clarification of previously provided information, and to request additional analysis/data from a conducted study. CTP's FY 2023 and FY 2024 targets are a reduction from our FY 2022 actuals because we are strategically reallocating resources from this pathway to

support the PMTA pathway. Targets are expected to increase through FY 2024 as CTP continues to hire more staff to review applications.

These application review performance measures have been selected because they demonstrate completion of specific milestones in the review of EX REQ, SE, and PMTA applications, and going forward represent the culmination of a significant amount of effort that aligns with CTP's current priorities. Taken together, these measures provide a complete representation of the Center's application review efforts.

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" cigarettes prevention campaign and "The Real Cost" and "Next Legends" e-cigarette prevention campaigns are active in market.

PROGRAM ACTIVITY DATA

CTP Workload and Outputs	FY 2022 Actuals	FY 2023 Estimate	FY 2024 Estimate
Tobacco Retailer Inspections			
Number of Inspections	93,065	90,000	110,000
Tobacco Manufacture Inspections			
Number of Inspections [1]	1,134	1,050	1,050

[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 2022 actuals and outyear estimates include vape manufacturer inspections conducted by contractors.

Figure 60 - CTP Workload and Outputs

FDA HEADQUARTERS

PURPOSE STATEMENT

FDA Headquarters (HQ) 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 HQ 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 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
FDA Headquarters	**308,089**	**313,207**	**331,099**	**364,323**	**423,031**	**58,708**
Budget Authority 1/	***186,919***	***193,213***	***205,981***	***224,940***	***301,264***	***76,324***
User Fees	***121,170***	***119,994***	***125,118***	***139,383***	***121,767***	***-17,616***
FTE	**954**	**944**	**941**	**963**	**1,072**	**109**

1/ FDA Headquarters Budget Authority shown inclusive of the $1.5M OIG transfer amount

Figure 61 – FDA Headquarters Funding History Table

The FY 2024 President's Budget for FDA Headquarters is $423,031,000 of which $301,264,000 is budget authority and $121,767,000 is user fees. The budget authority increases by $76,324,000 compared to the FY 2023 Enacted Budget. User Fees decreases by -$17,616,000.

FDA HQ will continue to provide policy direction and oversight, advance scientific development, and provide oversight of the global supply chain. FDA HQ will continue working 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 HQ along with the Centers and Offices, will evaluate and improve the effectiveness of preventive control standards, and advance the development of predictive safety models. FDA HQ will coordinate 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 HQ will continue to provide program direction and administrative services, ensuring FDA's public health mission is managed effectively and efficiently. FDA HQ is committed to delivering cutting-edge technology, innovation, and support to all stakeholders.

BUDGET AUTHORITY

FY 2024 President's Budget: Headquarters *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Enacted	**224,940**
FY 2024 Budget Authority Changes	**76,324**
Enhancing Food Safety, Nutrition & Cosmetics	**6,930**
New Era of Smarter Food Safety	1,430
Food Supply Chain Continuity	3,000
Modernization of Cosmetics Implementation	2,500
Advancing Medical Product Safety	**48,416**
ACT for ALS	416
Reigniting Cancer Moonshot	48,000
Investing in Core Operations - Crosscutting	**16,208**
Enterprise Data and IT Modernization	1,388
Public Health Employee Pay Costs	7,607
OC Regulatory and Mission Support	7,213
Other Adjustments	**4,770**
ORA Transfer to HQ/OGPS	24,200
Comparability Adjustment	(19,430)
FY 2024 Budget Net Total: Headquarters	**301,264**

Figure 62 – FDA Headquarters Budget Authority

Food Safety: $6.9 million / 8 FTE

New Era of Smarter Food Safety: +$1.4 million / 2 FTE

The FY 2024 Budget provides $37.0 million for the New Era of Smarter Food Safety, including an increase of $1.4 million for FDA Headquarters. The Budget builds on the funding requested in the FY 2023 Budget to continue progress towards the goals of the New Era of Smarter Food Safety.

In order to better prevent foodborne illness, the FY 2024 Budget provides additional resources for the FDA HQ to continue to improve predictive analytics, as well as make targeted investments in food safety culture. FDA will continue to expand collaboration on new data sources and tools with domestic and international public health partners, regulatory partners, academic institutions, industry, and others, building on lessons learned from the infant formula supply chain crisis. FDA will also continue efforts to incorporate behavioral science principals as a critical component of our food safety work in order to strengthen food safety culture on farms, in food facilities, and in homes.

Food Supply Chain Continuity: +$3.0 million

The FY 2024 Budget includes $3.0 million within Headquarters for data and analytics investments that will strengthen the agency's ability to assess the health of supply chains and inform efforts to respond to shortages of critical foods. Recent events, such as the COVID-19 pandemic and current infant formula shortage, have illustrated the challenges posed by

significant food supply chain disruptions, imbalances, and shortages. Ensuring the security and continuity of the food supply chain is also important to broader food security and equity issues. FDA regulates 80% of the U.S. food system and is therefore uniquely positioned to contribute data about food firms and facilities that can assist response efforts across government and the world.

The Budget will provide support for the agency's 21 Forward food supply chain continuity system, which has helped track supply chain shortages during the COVID-19 pandemic and inform ongoing work to track and anticipate supply disruptions across the infant formula supply chain. Resources will allow FDA to integrate additional internal and external data sources into the 21 Forward food supply chain continuity system. These additional data sources include commercial data on the marketplace and foods sales down to the UPC and food label, providing insight into product availability and composition that may be leveraged for multiple purposes across the FDA Foods Program. FDA will also further enhance the 21 Forward system with AI/ML algorithms to convert these large data sets into actionable intelligence.

Modernization of Cosmetics Implementation: +$2.5 million / 6 FTE

The FY 2024 Budget provides an increase of $5.0 million for Modernization of Cosmetics Implementation, including $2.5 million for FDA Headquarters. The FY 2024 Budget will position FDA to begin efforts to facilitate industry compliance with and provide effective regulatory oversight of cosmetic products.

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 challenges such as asbestos contamination of talc-containing cosmetics, tattoo inks and permanent makeup, and hair products (shampoo and conditioners). These resources will also strengthen aid FDA's post-market surveillance systems and enhance FDA's efforts to protect consumers from unsafe cosmetics.

Medical Product Safety: $48.4 million/ 37 FTE

ACT for ALS: +$416,000 / 2 FTE

The FY 2024 Budget provides $2.5 million in new sources for operational implementation of ACT for ALS Act, including $416,000 for FDA Headquarters to implement the new grant program in Section 5.

Although activities under the ACT for ALS Act were mandated by Congress in 2021, FDA has not received any direct funding for operational implementation. The FY 2024 funding will cover the operational needs to implement and maintain specific sections of the ACT for ALS Act-specifically, the Public Private Partnership (Section 3), Action Plan (Section 4), and the FDA Rare Neurodegenerative Disease Grant Program (Section 5).

Specifically, for grants and contracts pursuant to Section 5, the FY 2024 Budget funds will cover the costs of new infrastructure and resources, including: (1) hiring two new FTEs; and (2) coverage of operational infrastructure associated with managing a new grant program.

A dedicated source of operational funding to support Section 5 of the ACT for ALS Act will ensure that we will be able to optimally deliver on the activities mandated by the new law.

Reigniting Cancer Moonshot: +$48.0 million / 35 FTE

The FY 2024 Budget provides an increase of $48.0 million for Cancer Moonshot, all of which is within FDA Headquarters for the Oncology Center of Excellence.

To support the President's efforts in reigniting the Cancer Moonshot, FDA is committed to increase diversity and speed progress against the most deadly and rare cancers, including childhood cancers, by investing resources in research, education, and related activities as well as expand programs that address development of diagnostic and therapeutic products to benefit rare cancers and foster development of novel therapeutics for patients with ultra-rare cancers. In FY 2024, FDA will enhance efforts to expand resources and collaborations to improve evidence generation for underrepresented subgroups in oncology clinical trials, and to support pragmatic and decentralized trials and our sources of evidence through patient-generated data, learnings, and real-world evidence. FDA will advance the oncology Facilitate Call Center to support patients, caregivers, and survivors, and expand access networks to provide patients with cancer options for receiving novel/investigational therapies when a clinical trial is not available to them

Crosscutting: $16.2 million / 21 FTE

Public Health Employee Pay Costs: +$7.6 million

The FY 2024 Budget provides $105.3 million in new budget authority to fully fund anticipated increases in FDA's public health employee pay costs associated with the FY 2024 Cost of Living Adjustments (COLA), with an assumed pay increase of 5.2% for Civilian and Military FTE funded through budget authority. Within FDA Headquarters, $7.6 million is provided for pay costs.

OC Regulatory and Mission Support: + $7.2 million / 19 FTE

The FY 2024 Budget provides $15.8 million to advance high priority to provide the appropriate strategic direction, policy coordination, and crosscutting services to ensure that FDA's programs operate effectively, efficiently, and are well-coordinated. The request includes funding for:

Office of Policy, Legislation and International Affairs

The Office of Policy, Legislation and International Affairs is the Agency's lead for directing engagement across the multiple organizations in FDA, HHS, OMB, The White House, Congress, and other officials across the US Government in the development, coordination, and issuance of FDA's policies; economic and public health analysis; state, local, Tribal, and territorial government engagement; and global policy and strategy. The Office supports initiatives requiring extensive coordination across multiple workstreams, review of all COVID-related documents and other regulatory initiatives and development of related economic analyses. The Office provides extensive briefings, engagement, and coordination with stakeholders. The FY 2024 Budget will allow FDA to build needed additional capacity within this critical and under-resourced regulatory and policy development and coordination Office.

Office of Operations

The FY 2024 Budget will further investments to strengthen and meet demands for agency-wide Essential Services. These efforts include strengthening recruitment, retention, and other human capital efforts, continuing work to oversee and execute FDA's over $6 billion in annual resources and close to additional $1 billion in COVID-19 supplementals, and continuing to address critical infrastructure technical engineering services to manage and oversee FDA's presence at over 360 buildings across the nation.

Enterprise Transformation

In recognition that FDA traditionally has taken a Center or Office-based approach to common business processes, data management, and technology solutions which has led to challenges in communication, data sharing, and duplication of technology, the FY 2024 Budget proposes funding to support high priority agency-wide projects to analyze, optimize, and implement common business processes to improve operational efficiency and use of our data. This work will focus on critical enterprise areas to harmonize common processes, data collection/reporting, and systems to improve the efficiency of systems and processes at FDA. By providing funds to create sustained capacity, FDA will be positioned to successfully coordinate high complexity projects that will allow the agency to build and maintain enterprise business processes to more efficiently support FDA's mission.

Cannabis Regulatory Policy Coordination

The FY 2024 Budget will provide expanded capacity to advance cannabis product regulatory policy within the Office of the Commissioner. FDA will advance work in support of the agency's Cannabis Product Committee to manage policy coordination, cross-cutting scientific initiatives, and legal review associated with policy development activities, ensuring compliance with regulatory pathways, reviewing documents, and developing guidance.

This rapidly evolving, complex, multi-billion-dollar sector is posing increasing risks to public health, creating major policy challenges for several FDA program areas, and is of significant interest to a variety of stakeholders including consumers and Congress. FDA continues to experience a significant increase in activity and demands and the FY 2024 Budget will provide increased staffing to better manage this issue from the policy and legal perspectives. The additional funds within the Office of the Commissioner and the Office of the Chief Counsel will support staffing to support crosscutting policy development activities, extensive legal review for Cannabis Derived Product-regulated activities, enforcement to address the large number of Cannabis Derived Products that pose risks to public health, and communication of public health messages to alert consumers about public health risks.

Office of the Chief Scientist

Finally, the FY 2024 Budget will build on the FY 2023 President's Budget to develop and implement a cross-agency New Alternative Methods Program by providing additional funding within the Office of the Chief Scientist. This funding will support the New Alternative Methods Program by providing strategic coordination, implementation, and oversight and operational dollars to develop a qualification process to assess NAMs for regulatory use, especially those intended to replace, reduce, and refine animal studies (the 3Rs).

Immediate Office of the Commissioner

The FY 2024 Budget will provide additional central policy and leadership support within the Immediate Office of the Commissioner.

Enterprise Data and IT Modernization: +$1.4 million / 2 FTE

The FY 2024 Budget provides an increase of $10.0 million, for a total of $28.0 million, including $1.4 million for FDA Headquarters, to support FDA data modernization by building core programs and infrastructure aligned to the specific needs in both FDA's foods and medical product programs as well as the critical enterprise technology capabilities. The Budget supports FDA's coordinated data modernization agenda that includes centralized resources and capabilities plus program-specific customization.

The pandemic highlighted the need for a shared, cross-agency approach to Information Technology. The FDA began its digital modernization journey in September 2019 with the release of the Technology Modernization Action Plan (TMAP), followed by the Data Modernization Action Plan (DMAP) in 2021, and the Cybersecurity Modernization Action Plan in 2022. The action plans outline the agency's vision to modernize technology and data, enhance operational efficiency and use of data, while strengthening the alignment between agency-wide strategic objectives and IT investments, in a safe and secure technology environment. DMET related funding will be directed towards constructing a more robust data and technology infrastructure to better handle changes in the FDA's operational landscape, specifically in our ability to handle the increases in data being created from industry. Furthermore, the FDA is seeking an infrastructure that will better scale during public health emergencies. FY2024 DMET funding will aid the FDA's efforts to:

- Modernize operations and prepare for future public health crises. FDA will shift the technical infrastructure from a siloed and fragmented way of solutioning to a shared environment.
- Support enterprise data strategy efforts designed to improve operations though enhanced analytics and data visualization capabilities.
- Facilitate enterprise level efforts to build, scale, and operate an advanced data architecture and infrastructure, thus allowing technology to serve as a force multiplier to the FDA programs.
- Modernization activities supported by DMET will improve IT cost efficiencies as the FDA moves away from expensive to maintain on-prem Data Centers to scalable Cloud-based solutions.

USER FEES

Current Law User Fees: -$17.6 million

The FY 2024 Budget includes a decrease of -$17.6 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

HQ provides strategic leadership and coordination to enhance FDA's oversight of production, manufacturing, the global supply chain, and post market product use. FDA HQ provides policy direction and expertise to establish standards and guidance to protect patient and consumer safety. FDA HQ 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 HQ's delivery of its regulatory and public health responsibilities within the context of current priorities[114].

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** - provides outstanding operational and strategic human capital services to support this world class institution.

[114] Please visit http://www.fda.gov/ for additional program information and detailed news items.

- **Office of Security Emergency Management** - 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** - provide high quality and efficient HR solutions that enable the FDA to hire a talented and qualified workforce.

Office of Food Policy and Response

Infant Formula

The FDA has been leveraging a number of flexibilities to bolster 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 continues to dedicate all available resources 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.

To help ensure the continuity and resiliency of the food and agriculture sector, FDA developed a data analysis tool called 21 *Forward* to provide a comprehensive, data-backed understanding of all nodes in the food supply chain. FDA is monitoring the status of the infant formula supply by using the agency's 21 Forward food supply chain continuity system, combined with external data. The Agency is also Compiling data on trends for in-stock rates at both national and regional levels to help understand whether the right amount of infant formula is available in the right locations, and if not, where it should go.

New Era of Smarter Food Safety TechTalk Podcast Series

As part of New Era, FDA has been doing outreach in the form of podcasts. FDA's quarterly TechTalk podcast series, which focuses on the development and use of new technologies to strengthen the ability of FDA, regulated industry, and others to accelerate prevention, speed outbreak response, and more swiftly adapt to crises that could affect the human and animal food supply. In March 2022, FDA held its third TechTalk podcast focused on artificial intelligence and its potential to advance food safety. The podcast explored the potential for novel technological approaches in each of the core elements of New Era. In October 2022, the fourth TechTalk podcast focused on efforts to streamline and enhance data sharing between FDA and its regulatory partners at the state and local levels. All podcasts were widely listened to, with interest still high.

Produce Safety

FDA and partners in the public and private sectors have worked to enhance the safety of leafy greens through the development and implementation of the Leafy Greens STEC Action Plan (LGAP). This work includes prioritized inspections, focused sampling, stakeholder engagement and collaboration, data sharing, root cause investigations, and advancements in the science of detection and prevention.

December 2021, FDA issued a proposed rule addressing pre-harvest agricultural water provisions of the Produce Safety Rule (PSR) for covered produce other than sprouts. It proposes to require farms to conduct comprehensive assessments that would help them identify and

mitigate hazards in water used to grow produce. In addition, the agency has released resources and participated in engagement opportunities to help stakeholders better understand the proposed requirements.

In January 2022, FDA released a report on its investigation of the Salmonella Typhimurium outbreak that caused 31 reported illnesses and four hospitalizations in the U.S. between June and August 2021. The agency identified certain conditions and practices that could result in contamination, including the presence of a different serotype of Salmonella in pond water used to grow the leafy greens, growth media storage practices, water management practices, and general sanitation practices at the CEA that were inadequate to prevent the introduction or spread of microorganisms of public health significance into the leafy greens.

In July 2022, the FDA issued a supplemental notice of proposed rulemaking (SNPRM) to the agricultural water proposed rule to extend the compliance dates for the proposed pre-harvest agricultural water provisions. The SNPRM clarifies that FDA intends to continue enforcement discretion for the harvest and post-harvest agricultural water requirements of the Produce Safety regulation.

FDA-Mexico Food Safety Partnership

In October 2020, the United States and Mexico officially launched the FDA-Mexico Food Safety Partnership2 (FSP), broadening and strengthening the scope of our existing partnership to include the safety of all human food regulated by the FDA. To implement the FSP, four work groups have been established with membership from the FDA, SENASICA and COFEPRIS to increase cooperation in the areas of: strategic priorities, laboratory collaboration, outbreak response and prevention, and food safety training.

Since September 2020, through collaborative efforts with SENASICA and the Mexican papaya industry, more than 300 growers have been trained on the Produce Safety Alliance's grower-training curricula and about 90% of the Mexican papaya industry has been trained on papaya best practices. The partnership will continue to strengthen work with industry on Foreign Supplier Verification Programs (FSVP) trainings for importers and the verification of papaya best practice implementation. As a result of this partnership there have been no further outbreaks of salmonella linked to papayas in 2020 and 2021.

Over the last year the partnership has continued to facilitate outreach and training in multiple languages on the FDA's PSR and FSVP rule for the produce industry. SENASICA and COFEPRIS worked with the FDA to promote virtual webinars across Mexico. In addition, FDA has launched a new Web page, which includes resources in both English and Spanish, to communicate the progress of the FSP to stakeholders.

August 25 2022, FDA and its regulatory counterparts in Mexico. SENASICA and COFEPRIS held the second annual Food Safety Partnership meeting as part of the ongoing efforts to help ensure the safety of food imported from Mexico and to advance protections for consumers in both countries.

Office of External Affairs

Communication Products for Consumers, Health Care Professionals and Others

FDA HQ 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 April 1, 2021 through October 31, 2022, FDA's Office of External Affairs issued or held:

- 359 MedWatch Safety Alerts (FDA's second largest e-list) to over 399,775, subscribers and approximately 55,000 MedWatch Twitter followers;
- Approximately 400 news releases and other press announcements in English and/or Spanish to more than 100,000 subscribers;
- Roughly 45 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 135,000 subscribers in English and 39,000 in Spanish; 150 Consumer Videos with 683,861 views and 129,038 subscribers; 47 FDA Voices perspective articles, sent to 103,000 subscribers; 70 newsletters in English, which reach approximately 71,000 health care professionals, consumers and patients, and targeted emails to specific organizations; and 25 newsletters in Spanish with over 8,300 subscribers;
- Approximately 156 Stakeholder Calls with the FDA Commissioner and senior agency leadership; issued over 247 targeted stakeholder outreach emails; 250 tweets and 125 Facebook posts per month with an estimated 18 million views. Of note, FDA has 1.8 million followers on Office of External Affairs accounts, and 3.25 million followers on all social media accounts across FDA.

Communication with Stakeholders – Improvements to FDA.gov and Social Media Channels

Throughout 2021 and 2022, FDA continued to make data-driven, iterative improvements to its public-facing website, FDA.gov. This included regular updates to FDA's landing page for COVID-19. Through the first two years of the pandemic this page grew considerably. It serves as the Agency's hub to provide visitors with vital information on vaccines, testing, personal protective equipment, and Emergency Use Authorizations (EUAs). By regularly reviewing the analytics of the COVID-19 content, FDA is able to better understand the information being requested by our stakeholders and ensure that COVID-19 related information is easy to find. In addition, FDA conducted usability testing of FDA.gov during December 2021 to improve the usability of the website by having actual users of the site perform specific tasks. This round of usability testing focused on the consumer audience's use of mobile devices and was required as part of the 21st Century Integrated Digital Experience Act.

As a result of this testing, OEA has made significant improvements to the "About FDA" section of FDA.gov and will be replacing the current search capability with an improved search engine in August 2022. FDA launched an Instagram account to expand stakeholder reach and enhance message dissemination on critical public health issues with new audiences and younger populations. To date the account has over 73,000 followers and over 250 images have been shared.

FDA HQ 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. In addition, this mobile-friendly and easy-to-use product simplifies the process of sending emails for FDA administrators who manage the email lists. Currently, FDA has over 190 content topics available and over 1 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.

Throughout 2021 and 2022, FDA coordinated calls and conducted outreach with groups on a variety of COVID-19 topics, including Agency announcements related to vaccines, therapeutics and testing. In addition, FDA held engagements and conducted outreach with stakeholders concerning other Agency priorities, such as the Closer to Zero Action Plan for baby food, sunscreen quality and efficacy, tobacco regulation, infant formula shortages, overdose prevention, Monkeypox, and combating misinformation/disinformation efforts particularly around COVID-19 vaccines.

Since April 2021, FDA HQ coordinated over 15 listening sessions to gather stakeholder concerns, feedback, and useful information on opioids mandatory prescriber education and regenerative medicine therapies, including certain human cells, tissues, or cellular or tissue-based products (HCT/Ps).

In an effort to increase transparency, FDA posted video recordings of 22 stakeholder calls on FDA's YouTube page, which has over 124,000 subscribers. From April 2021 to the present, these videos have been viewed over 163,000times. Following all stakeholder calls, FDA disseminates recordings on Agency social media platforms. FDA HQ used social media to engage with stakeholders via Facebook, multiple Twitter accounts, YouTube, and other channels. The Agency conducted five Twitter chats, including three targeting a bilingual (English- and Spanish-speaking) audience.

Finally, FDA HQ managed 1,421 speaker requests received from over 257 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 2022, FDA HQ received and processed 41 formal Request for Designation (RFD), and evaluated and completed 49 informal Pre-RFD submissions regarding product jurisdiction. In addition, FDA HQ provided jurisdictional feedback for 77 center requests. These decisions and feedback ensure products are properly regulated.

In FY 2022, FDA HQ helped ensure close cross-center coordination of CP activities by providing support for approximately 1936 inter-center consults (ICCR), 33 CP postmarket activities, and 81 product-specific requests. These activities contributed to ensuring the timely and effective review and postmarket safety of CPs.

In FY 2022, FDA HQ continued to improve our IT systems to increase functionality and efficiency, and to harmonize workflow and data collection. In addition, FDA HQ developed an IT solution that integrates CP data from different sources including premarket registration & listing and adverse event reporting systems from all three medical product centers, which enhances the efficiency of conducting FDA's postmarket safety surveillance activities for CP.

In January 2022, FDA HQ published a final guidance "Principles of Premarket Pathways for Combination Products" which discusses FDA's risk-based approach to CP regulation, a framework for premarket regulation, and opportunities for sponsors to leverage prior agency actions. It also ensures aligned premarket expectations across Agency Centers and minimized burden, as codified in section 3038 of the 21st Century Cures Act. In September 2022, FDA HQ published a final listing in the Federal Register of "Alternative or Streamlined Mechanisms for Complying with the Current Good Manufacturing Practice Requirements for Combination Products" as mandated by section 3038, which reduces the burden for sponsors to demonstrate compliance with cGMP requirements. FDA HQ also continued to lead or participate in the development of important guidance documents mandated by statute or requested by stakeholders (e.g., technical data and human factor requirements for drug delivery devices). FDA HQ participated 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 HQ continued collaborations with Agency Centers and external stakeholders to increase the availability of safe and effective medicines for children. By September 2022, FDA completed more than 1,000 pediatric labeling changes for drugs and biologics, reflecting the hard work of the medical product Centers and the strength of the laws and regulations pertaining to pediatric clinical trials. Additional details can be found in the second quinquennial report to Congress.

In FY 2022, for example, FDA HQ:

- 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 132 issues discussed in FY 2022, the most frequent topics were scope of pediatric development and clinical study design.
- 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 HQ completed more than 90 consultations in FY 2022 and continued work to develop guidance documents, including the FDA Draft Guidance entitled Ethical Considerations for Clinical Investigations of Medical Products Involving Children.

- 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 2022, we completed 24 pediatric-focused product safety reviews of drugs, biologics, vaccines and devices.
- Promoted neonatal product development through multiple collaborative efforts, such as: 1) guidance development; 2) work with neonatal consortia to develop tools to streamline development; and 3) providing neonatal-perinatal medicine consultations across the Centers, with 73 consults completed in FY 2022.

Patient Engagement

FDA HQ Patient Affairs Staff (PAS) continued patient-focused initiatives of cross-cutting interest to all FDA medical product centers. This included triaging and responding to inquiries from patients, caregivers, and patient organizations. The FDA Patient Listening Sessions includes collaborators such as the National Organization for Rare Disorders and the Reagan-Udall Foundation. The Clinical Trials Transformation Initiative (CTTI) is the collaborator for the Patient Engagement Collaborative in which external outreach with presentations were conducted and work was closely coordinated with the internal FDA Patient Council. 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 HQ led the development of two notices of proposed rulemaking (NPRM) that published in September 2022, one that would mandate use of a single institutional review board (IRB) for cooperative research in the U.S and the other harmonizing certain provisions of FDA's informed consent and institutional review board requirements. FDA HQ is in the process of finalizing a previously issued 2018 proposed rule that would 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 addition, FDA HQ 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. In FY 2022, FDA HQ also continued to serve as ex-officio on the Secretary's Advisory Committee on Human Research Protections (SACHRP). More broadly, FDA HQ supported over 40 cross-agency policy efforts related to human subject protections, good clinical practice, and clinical trial modernization

Finally, FDA HQ 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 76 Preliminary Notices of Noncompliance with the ClinicalTrials.gov requirements, and 4 Notices of Noncompliance to responsible parties for applicable clinical trials. FDA HQ 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

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. Although there are over 7000 rare diseases that collectively affect more than 30 million Americans, prior to the incentives established by the ODA, there was little market interest in developing medical products for rare diseases.

- Orphan Products Grants Program (OPGP) comprised of the Clinical Trials Grants Program and the Natural History Studies Grants Program;
- FDA Rare Neurodegenerative Disease Grant Program; and
- Pediatric Device Consortia Grants Program.

OOPD also administers three designation programs—Orphan Drug Designation Program, Humanitarian Use Device Designation Program, and Rare Pediatric Disease Designation Program.

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 2022, five products were FDA-approved using CTGP support that in aggregate, can help approximately 100,000 individuals who otherwise had little hope. The products are: Rethymic, Fyarro, Orencia, Terlivaz, and Tavneos. Among these, four are notable for being the first pharmaceuticals ever approved for these rare diseases. Previously, individuals with these diseases had no pharmacologic options. For example, children with congenital athymia (CA) have defective development of the thymus gland causing a propensity for certain life-threatening infections—a very rare and devastating disease. With approval of Rethymic, children with CA in the U.S. now have an FDA-approved treatment.

In addition to the five approved products funded by our CTGP, in FY 2022, OOPD also awarded eleven new grants of which eight target rare cancer treatments with significant unmet needs. Two of these new awards are for clinical trials investigating novel treatments for glioblastoma—an aggressive form of brain cancer which is almost always fatal within a year of diagnosis. We also continued investments for approximately 70 other ongoing clinical study projects, including eight Phase 3 trials that will 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 2022, OOPD funded eight new NH studies for rare diseases that are poorly characterized and two ongoing natural history studies that will be used to learn more about these uncommon diseases.

With the enactment of the *ACT for ALS Act* on December 23, 2021, Congress established the FDA Rare Neurodegenerative Disease Grant Program. Grants or contracts may be awarded to cover the costs of research and development of interventions intended to prevent, diagnose, or treat ALS and other rare neurodegenerative diseases in adults and children.

In FY 2022, five projects that align with the goals of FDA Rare Neurodegenerative Disease Grant Program—two contracts and three grants—were funded with the base increase of $2.5 million in the OPGP. OOPD received additional contributions from NIH and FDA CDER for a total FY 2022 investment of $5.8 million. The projects are:

1. A contract to adapt and validate a commonly used endpoint used in ALS clinical studies for remote use. Having a remote use tool will decrease travel burden on patients and families in future clinical trials and help remove obstacles for subject recruitment and retention that often leads to underrepresentation of certain groups of otherwise eligible subjects in clinical trials.

2. A contract for a landscape analysis of brain-computer interface (BCI)-focused patient preference information studies in ALS patients. BCIs are devices that can be implanted in the brain to aid communication with loved ones, caregivers, and providers as ALS progresses. Equity requires that we invest to help patients at all stages of their disease—especially those who cannot speak for themselves as is often the case with end-stage ALS. Specifically, this project will determine whether patient preference data adequate for regulatory decision making exists in anticipation of future product reviews for BCIs. If such data does not exist, then we may plan an FDA-sponsored study to obtain the needed data.

3. Three NH studies grants for rare neurodegenerative diseases that align with the goals of the *ACT for ALS Act*, including:

- A comprehensive NH study to characterize ALS that leverages an established multi-institutional infrastructure and has the ability make great impact on our understanding of ALS, inform drug development, and possibly support future regulatory decisions.
- A prospective NH study in Myotonic Dystrophy Type-1—a type of adult-onset muscular dystrophy—to establish biomarkers and clinical endpoints for use in clinical trials.
- A NH study in Ataxia-Telangiectasia (AT) leveraging the world's largest AT patient group to collect data on patients and validate a newly developed AT-specific functional scale to be used in the future to measure the effectiveness of drug interventions.

The Pediatric Device Consortia (PDC) Grants Program is intended to encompass devices for all pediatric diseases and conditions, not just those that are rare. The program provides expert advisory services and funding to facilitate device development specific to the unique needs of children supporting a critical public health need. The PDC provides a platform of experienced regulatory, business planning, and device development services to help foster and guide advancement of medical devices for pediatric patients.

For the grant reporting period (September 2021-August 2022), the PDC assisted 611 pediatric medical device projects. As a direct result of their efforts in FY 2022, one device (EaseVRx) was granted a De Novo classification and three PDC supported devices received 510(k) clearance for use in pediatric patients: EvoEndo Single-Use Endoscopy System, Orchid Safety Release Valve, and InfraScanner. In addition, the PDC hosted three Pediatric Device Innovators Forums—a recurring collaborative educational experience designed to connect and foster synergy among innovators. This fiscal year, OOPD funded five geographically dispersed consortia, creating a

national network committed to improving health equity for pediatric patients in the medical device space.

Office of the Chief Scientist

Centers of Excellence in Regulatory Science and Innovation

FDA HQ provides leadership, coordination and support for four academic Centers of Excellence in Regulatory Science and Innovation to provide FDA scientists ready access to leading researchers to assist in addressing high-priority regulatory science questions. The four Centers of Excellence are Johns Hopkins University, Yale University with Mayo Clinic, University of Maryland, and the University of California San Francisco with Stanford University. In FY'2022, twenty-two newly established collaborative research projects include addressing the COVID-19 pandemic, the opioid epidemic, oncology underrepresented populations, real-world evidence, product safety, and digital health.

Chief Scientist Challenge Grants

FDA HQ established, and now manages and coordinates the review and granting of an 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'2022, the Chief Scientist Grants Program funded twelve projects that reflect the overarching scientific priority areas for FDA and were recognized as highly innovative and high-risk. All projects involve cross-agency collaborations that display rigorous thought, focus, and excellent scientific merit. The scientific areas of the recent projects include COVID-19 pandemic, batteries for implants, cytokine release syndrome and neurotoxicity during CAR T cell therapy, biomarkers for oncology, nanosensing for foodborne viral pathogens, detection of radiation in the Nation's food supply, bioprinted human skin, and postmarket product safety and surveillance.

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 in the area of 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, FDA to successfully engaged with external partners to advance regulatory science initiatives, participated in the federal technology transfer mandate through reporting inventions, and updated its knowledge of methods to increase the utilization of inventions through collaboration and transfer.

Global Health Security

FDA HQ provides 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 Monkeypox virus
- providing leadership and coordination for FDA responses to health security threats.

Key FY 2022 – FY 2023 FDA HQ 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 over 70 EUAs to enable the emergency use of hundreds of medical products (including diagnostic tests, vaccines, and treatments), numerous amendments to current EUAs upon request from the product manufacturers to add additional instruments or specimen types or make clarifications, and numerous EUA revocations; working closely with interagency partners and regulated industry to identify and mitigate supply shortages of FDA-regulated products; and continually communicating FDA's Agency-wide response efforts (including well over 100 press releases, hundreds of email updates, and numerous other communications, including web updates, videos, and social media to help promote confidence in the public health response) and sustaining intensive stakeholder outreach (including town hall meetings, webinars, workshops, email alerts, and individual outreach).[115]
- Working to improve EUA processes and promote supply chain resilience based on recommendations from the FDA PREPP Initiative.
- Continuing to facilitate coordination of FDA response activities to Ebola outbreaks in Africa, the Monkeypox in non-endemic countries, and other emerging infectious disease outbreaks including the issuance of EUAs to enable access to available medical countermeasures when necessary.
- Supporting monitoring for products with unsubstantiated or fraudulent claims for the diagnosis, treatment, or prevention of COVID-19, Ebola and Monkeypox
- Supporting domestic and international policy development activities related to COVID-19, Ebola and Monkeypox virus response including providing technical support to the World Health Organization and international regulatory counterparts.

[115] More information about FDA's COVID response efforts is available on the FDA website at: www.fda.gov/coronavirus

- Continuing to work to resolve MCM shortages as quickly as possible when they occurred. For example, FDA HQ provided critical leadership through the USG 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.
- Continuing to support a 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.
- Continuing to provide public information and education on FDA preparedness and response activities via events, press releases and interviews, the FDA website and social media.

Office of Laboratory Safety

The Office of Laboratory Safety (OLS) serves as the Agency coordinator and lead for 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. These activities also include OLS-led inspections of FDA's laboratories and implementing agency-wide initiatives related to compliance with occupational safety and health standards. 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 standards and policies; quality and safety assessment and improvement strategies; and other activities that emphasize the benefits of a safety-oriented culture.

In FY2022, OLS published 6 new safety manuals; offered 6 new trainings; conducted numerous safety inspections of FDA laboratories; conducted environmental compliance audits; and published a workplace incident report, an annual safety inspection 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

FDA HQ 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. OWH research also aims to promote a better understanding of medical conditions that disproportionately or solely affect women and strives to advance the science of FDA products used during pregnancy and lactation

OWH supports women's health research funding both intramural and extramural research. In FY 2022 the Intramural Research Program committed funds for seven new projects on a wide variety of topics relevant to women, including studying the impact of COVID-19 on female fertility, evaluating the impact of dose response interruptions on the efficacy of breast cancer drugs, understanding the safety of cardiovascular medical devices, and studying sex bias in artificial intelligence assessing the severity of COVID-19. 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.

In FY2022, OWH staff and funded investigators published a variety of manuscripts in peer-reviewed scientific and medical journals.

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; 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.

FDA Office of Women's Health develops educational initiatives and conducts outreach to connect women with FDA health and safety information. Utilizing 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 recognition of Fibroid Awareness Month in July 2022, OWH developed and launched new creative educational resources under the KNOWH initiative aimed at educating and raising awareness about uterine fibroids. The informational and testimonial video, new fact sheet, and link to dedicated blog post live on the dedicated webpage: www.fda.gov/uterinefibroids; and specific pages here: fact sheet- https://www.fda.gov/media/159840/download, dedicated blog page- www.fda.gov/OWHblog. The uterine fibroids landing page has garnered over 3,000 page views (or impressions) and over 595,000 video views of the full video, testimonial video and takedowns since launch.
- In November 2021, OWH launched new diabetes video under the KNOWH campaign, Be Empowered: Understanding Diabetes. This video highlights how diabetes can impact women differently and shares the unique experiences of women affected by diabetes. The full video has garnered nearly 10,500 page views and nearly 560,000cumulative video views since launch.
- For National Women's Health Week (NWHW) 2022, OWH hosted two public maternal health webinars, a blog post highlighting maternal health resources, and a toolkit for healthcare providers and health professionals. A NWHW post card promoting OWH health education materials was mailed to targeted colleges, universities, and sororities. A total of 395 orders were placed, distributing 102,950 publications.
- 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 implemented 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.

In May 2021 OWH hosted a Virtual College Women's Campaign (CWC) Meet and Greet with historically black colleges and universities (HBCU). HBCU representatives across the country participated and were provided resources to help students make informed decisions about their health. Under our CWC, OWH regularly shares health and safety information targeted to the college age demographic.

Since October 2021, OWH exhibited at ten health focused conferences (virtually and one in person) to share health education and FDA safety resources with thousands of stakeholders.

From October 2021 to October 2022, OWH has distributed over 1.3 million women's health education materials to various stakeholders and healthcare professionals. OWH materials are available electronically in multiple languages to download – www.fda.gov/womenshealthpubs.

From October 2021 to date, OWH updated the Pink Ribbon Guide: Mammography Matters, Cholesterol Medicines guide, and revised the Food Safety at Home fact sheet, and created a new Uterine Fibroids fact sheet and Uterine Fibroids: Tips for Young Women card.

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 2021 and December 2022, the OMHHE reached more than four million consumers through communications activities such as digital outreach, social media, blogs, weekly COVID-19 communications, and over 130 e-alerts, including the following:

- Hosted three Health Equity Lecture Series webinars on clinical trial diversity, health disparities and diabetes.
- Developed and released five new episodes of the Health Equity Forum podcast series on the following critical health areas: Diversity in Lupus Clinical Trials, Food Safety and Nutrition *(x2)*, COVID-19 Vaccines and Boosters Misinformation, and Hepatitis B Clinical Trial Diversity.
- Updated the COVID-19 Safety and Diversity public service announcement videos; and translated them into multiple languages, including Native languages and American Sign Language.
- Launched a Language Access Webinar Series and hosted two webinars; continued to lead the Language Access Volunteers Program with cross-agency native speakers to proofread materials for accuracy and cultural sensitivity.
- Launched the Skin Facts! What You Need to Know About Skin Lightening Products Initiative, a national multimedia campaign to provide education and alert consumers on the use of and potential risks from skin lightening products that contain hydroquinone or mercury. OMHHE collaborated with The Reagan-Udall

Foundation, CDER, and CFSAN to conduct formative research among diverse stakeholders to develop the campaign.

- 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 (Spanish, Arabic, Cherokee, Simplified Chinese, Traditional Chinese, French, Hindi, Korean, Navajo, Tagalog, and Vietnamese). Continued to promote the bilingual multimedia Let's Take Charge Initiative in partnership with the HHS Office of Minority Health to increase participation of racial and ethnic minority and tribal communities 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, and non-profit organizations to advance health equity-focused research, education, and scientific exchange. From October 2021 through December of 2022, OMHHE launched the Enhance Equity Initiative to support research projects and communication resources. Under the Initiative, OMHHE announced and funded three Notices of Funding Opportunities:

(1) COVID-19 and Health Equity Innovation Award ($5M) - funded five 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 regulatory communication. Institutions awarded included HBCU's, MSI's, and diverse organizations.

(2) Innovation Award: Minority Health and Health Equity ($3M) - funded seven projects to understand barriers to, and increase participation in, clinical trials, examine misinformation correction strategies, communicate health and safety information, and assess mobile community engagement strategies, among other areas that advance health equity. Institutions awarded include diverse organizations and academic institutions.

(3) OMHHE Educational Funding Opportunity: Expanding education on skin lightening products ($0.5M) - 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 skin lightening products containing hydroquinone. Institutions awarded include HBCU's and diverse organizations.

In addition, OMHHE announced two new FY23 Funding Opportunities, (1) Innovation Award: COVID-19 and Health Equity, and (2) OMHHE Educational Funding Opportunity: Expanding Education on Skin Lightening Products. OMHHE also conducted the following:

- OMHHE funded 2 BAA projects - one project with the American Indian Opportunity to advance equity in clinical trials for American Indian and Alaska Native communities, and a project to elevate Equity of Voices with the National Minority Quality Forum.
- OMHHE co-funded one CERSI project to advance equity in clinical trials for older racial and ethnic minority populations.
- OMHHE continued support and collaboration on five COVID-19 projects with Howard University, Yale University (Yale Cultural Ambassadors), Stanford

University, S-3 Research, and the U.S. Department of Veterans Affairs. Additionally, OMHHE continued to support projects to advance diversity in hepatitis B clinical trials with the Hepatitis B Foundation, and PrEP Therapy Among Minority Populations.

- OMHHE supported Challenge Grants focused on innovative, intramural minority health and health equity focused research through collaborations across FDA product centers and offices. During FY 2022, OMHHE awarded funding for four projects totaling $265,000.
- OMHHE continued to support internships and fellowships to expand expertise in regulatory science and diversify the scientific workforce. In FY 2022, OMHHE continued to co-lead and support the Postdoctoral Fellowship in Genomic Science and Health Equity, co-sponsored by the National Human Genome Research Institute (NHGRI) at NIH. The fellowship was selected as a winning proposal for the Secretary's Challenge on Equity. The office also precepted five 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 8 manuscripts in peer reviewed journals.

Office of Policy, Legislation and International Affairs

Advance FDA's Priority Rulemakings and Guidance Documents

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, as well as coordinating clearance and issuance of Federal Register documents. In FY 2022, for example, OP took a leadership role in responding to the Administration's Executive Order on competition, EO 14036. In particular, OP led FDA's engagement with the United States Patent and Trademark Office to identify opportunities to reduce barriers to generic drug and biosimilar competition and led FDA's engagement with the Administration around the policies contained in FDA's proposed and final rules to establish a new category of over-the-counter hearing aids. Reflecting OP's work on cross-cutting initiatives, in FY 2022, OP advanced FDA's policy work in response to the COVID-19 public health emergency (PHE), including leading FDA's effort to prepare for the potential future end of the PHE. 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 or more 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 COVID-19 response efforts, monkeypox, the opioid crisis, tobacco regulation, and more. On September 30, 2022, the FDA User Fee Reauthorization Act of 2022 was passed as part of H.R. 6833, the Continuing Appropriations and Ukraine Supplemental Appropriations Act of 2023. This five-year reauthorization of the human medical product user fee programs is the result of months of engagement with Congressional Members and staff, and is pivotal legislation that will help:

- strengthen the predictability and transparency of the human medical product review process;
- provide essential support for the agency's work to foster the availability of innovative medical products to the public; and
- facilitate the development and timely approval of lower-cost generic and biosimilar products.

FDA's legislative activity and engagements with Congress are increasing, particularly with ongoing interest and engagement related to pandemic preparedness, medical product supply chain resiliency, and development, and upcoming reauthorization of other user fee programs.

Office of Congressional Appropriations (OCA)

The Office of Congressional Appropriations (OCA) dual mission is to serve as a liaison to congressional appropriators and their staff in support of FDA's resource needs and its public health mission, as well as advise the FDA Commissioner and other senior leadership on appropriations and budget matters. Through the annual budget and appropriations process, OCA has worked with congressional appropriators to understand FDA's resource needs related to a number of 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. Over the past year, in addition to managing the Agency's outreach to Congress related to the fiscal years 2022 and 2023 budgets, 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 has also continued to work closely with FDA senior leadership to develop, refine, and effectively communicate the Agency's current, short-term, and long-term resource needs to respond to the COVID-19 public health emergency, as well as the current monkeypox outbreak and future pandemics.

Engagement with State, Local, Territorial and Tribal Officials

The Intergovernmental Affairs (IGA) staff, within the Office of the Commissioner's Office of Policy, Legislation, and International Affairs, is the lead staff in the Office of Commissioner that engages with state, local, and territorial stakeholders on issues covering the breadth of the Agency's regulatory responsibilities. IGA also engages with federal intergovernmental partners, including the White House, HHS, and other federal entities. In addition, IGA serves as the primary Agency liaison with tribal governments and tribal organizations, ensuring that the Agency does its part to honor and respect the unique government-to-government relationship that exists between the U.S. Government and federally recognized American Indian/Alaska Native tribes. IGA coordinates across all FDA Offices, Centers and/or other organizational components to fulfill its mission. In support of the Administration's commitment to ensure robust

engagement and consultation with tribes, IGA facilitates communication regarding FDA policy initiatives and serves as an entry point to tribal officials seeking assistance with matters under FDA's regulatory purview. IGA also manages formal consultation and engagement with tribal officials, guiding FDA Centers and Offices on the use of Dear Tribal Leader Letters (DTLL) and the tribal consultation process, and coordinates data calls regarding the Agency's interactions with tribal governments. IGA also serves as the interagency tribal liaison for the Agency, including with HHS and the Indian Health Service (IHS). From October 1, 2021, to July 31, 2022, IGA engaged with state, local, territorial, and tribal (SLTT) stakeholders, proactively and reactively, on a variety of issues, including: the Agency's response to the Public Health Emergency declared for both COVID-19, as well as mpox; cannabis; drug importation; compounding; food safety, including issues related to infant formula; opioids; stem cell therapies; tobacco; and many others.

Economic Analysis and Support for Regulations Published

FDA's Office of Economics and Analysis (OEA) builds the foundational data and knowledge base that informs and improves FDA's evidence-based policymaking. OEA's multidisciplinary staff works across the full range of FDA products and priorities, including but not limited to public health emergencies, market competition and industry structure, health equity, economic impact analysis of key FDA food, tobacco, and medical products 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 extent and causes of bottlenecks in the generic drugs and biosimilars markets, and the market dynamics and extent of competition in these markets, to identify appropriate policy levers to address these problems.

-Economic Analysis and Support for Regulations Published. FDA publishes regulatory impact analyses for all Agency proposed and final rules, while working under very tight deadlines and within unique legal constraints. 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. In the process of developing these analyses, OEA also provides briefings, presentations, and participates in substantive engagements with high level stakeholders within FDA, HHS, and OMB.

-GAO/OIG Engagements and Agency Responses. OEA's GAO/OIG Liaison team leads Agency responses to GAO and OIG studies, which have increased in number over the last few years, partly driven by the heavy volume of oversight related to the Covid-19 pandemic, the Abbott infant formula recall, and increased interest in guarding against political interference in scientific decision making. The Team ensures timely, accurate, and complete responses to GAO and OIG engagements, and coordinates the regular updates reporting progress on implementing the auditors' recommendations.

Office of Global Policy and Strategy

International Inspections, Information Sharing and Strategic Engagement, and Continued Implementation of China Safety Initiative

FDA engages strategically with global regulatory counterparts and stakeholders to assure that products coming to the U.S. market are safe and effective. FDA's Office of Global Policy and Strategy (OGPS) was formed after the OC reorganization in 2019 and is comprised of three headquarters offices (Office of Global Diplomacy and Partnerships; Office of Global Operations; and Office of Trade, Mutual Recognition, and International Arrangements) including 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 that report through the Office of Global Operations (OGO). 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.

OGPS activities include inspections in China, India, and Latin America and observed inspections with regulatory counterparts to enhance global inspectional capacity in China, India, and Mexico; advocacy in bilateral and multilateral settings for the importance of strong regulatory systems to enhance public health; representation of FDA's regulatory equities in trade negotiations and at the World Trade Organization; negotiation and development of international arrangements or agreements that facilitate the exchange of regulatory information and regulatory cooperation with our global counterparts.

Inspections

FDA foreign office staff as well as ORA investigators on short-term assignment to the China, India, and Latin America offices conduct inspections in their respective country or region. In FY2021, despite COVID-19 restrictions, OGPS performed 125 in-person inspections. To date in FY 2022, OGPS personnel have completed 102 foreign inspections in China (23), India (57), and Mexico (22). In addition to in-person inspections OGPS investigators performed 306 remote regulatory assessments of critical drug facilities and sites conducting clinical trials of drugs and biologics.

The OGPS India Office has a critical role in completing unannounced inspections, and in providing logistical and operational support for the unannounced inspection pilot program. The China Office is expected to begin performing unannounced inspections as part of the pilot program in mid FY-23, contingent on the easing of in-country COVID-19 travel restrictions in China.

Information Sharing and Strategic Engagement

FDA engages strategically to ensure accurate and timely information can be exchanged among regulators in support of information-driven decisions and actions. 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 2022, FDA established two new confidentiality commitments, one with India (human foods) and the other with the European Union (human/animal medical products and human

foods) to support FDA's information-sharing with foreign counterparts. In addition, the FDA established three new cooperative arrangements to enhance regulatory cooperation: the Republic of Korea (shellfish safety); Brazil (medical products and foods); and Ireland (caseins).

Recognizing the growing threat to information security, in FY 2022 FDA enhanced its confidentiality commitments to require foreign regulatory counterparts to adhere to new information security measures.

In FY 2022 FDA has had multiple strategic engagements to enhance health equity and ensure diversity in clinical trials. Through standing partnerships with European regulators and the United Kingdom, we have established an ongoing forum with a range of activities to build equity in clinical trials through ensuring collection of data relevant to use of drugs and biologics in the care of pregnant and lactating women. In addition to discussions of individual products and workshops launched through the International Coalition of Medical Regulatory Authorities (ICMRA), establishment of international standards for clinical trials in these neglected populations has been proposed and accepted by the International Coalition on Harmonization (ICH).

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 2021 and FY 2022, FDA's partnerships included multilateral institutions such as the World Health Organization (WHO), the Pan American Health Organization (PAHO), the Organization of Economic Cooperation and Development (OECD), the Asia Pacific Economic Cooperation (APEC), the Global Fund, the Gavi Vaccine Alliance, and the Inter-American Institute for Cooperation on Agriculture (IICA).

A new FDA initiative with OECD seeks to shed a spotlight on the growing public health threat of illicit trade in health products (medicines, medical devices, food) and raise the profile and awareness of this issue within the EU and global community, working with the OECD Task Force of Combatting Illicit Trade. This was launched over several months in FY2022 and is expected to continue to grow going forward. Within the WHO, under the auspices of the WHO Member State Mechanism for Substandard and Falsified Medical Products, OGPS initiated a working group on developing mitigation strategies to address substandard and falsified medical products sold in informal markets. The FDA chairs this working group, which complements the OECD Task Force described above. This work enables FDA to address the concern of illicit trade of medical products in multiple venues.

Leveraging the Authority of Foreign Regulators

OGPS is FDA's lead for the negotiation of Mutual Recognition Agreements. Title VII, Section 712 of the Food and Drug Administration Safety and Innovation Act (FDASIA) allows FDA to enter into written arrangements and agreements with foreign governments to recognize the inspection of foreign drug establishments for the purpose of facilitating FDA's risk-based inspection schedule. In FY 2021 and FY 2022, OGPS furthered implementation of the Revised Pharmaceuticals Annex to the United States – European MRA by completing 7 capability assessments of Member States for their ability to perform GMP inspections of veterinary drug facilities (5 for FY 2021, and 2 for FY 2022 year-to-date). OGPS also commenced negotiations

with Switzerland to facilitate a Mutual Recognition Agreement to rely on inspection reports by Swissmedic, Switzerland's regulatory authority for drugs and medical products.

Supply Chain Resilience

FDA continues efforts to support resiliency and redundancy in supply chains for both drugs and medical devices and OGPS plays a critical role in developing and expanding understanding of how foreign medical products and components are manufactured, regulated, and integrated into the global supply chain. OGPS continues to represent 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.

Oncology Center of Excellence

The Oncology Center of Excellence (OCE) was authorized by the 21st Century Cures Act of 2016 and established on January 19, 2017. The Center unites experts across the FDA to conduct expedited review of medical products for oncologic and hematologic malignancies. The OCE also leads a variety of research and educational outreach projects and programs to advance the development and regulation of medical products for patients with cancer. In FY2022, OCE's review and scientific collaboration has resulted in 61 publications summarizing oncology review products or regulatory science issues, 10 draft or final guidances, and substantive stakeholder engagement through the execution of 39 oncology symposia/workshops. International regulatory collaboration has been strengthened with Project Orbis and other outreach. Clinical review of cancer products was supported by OCE Medical Oncology Review and Evaluation (MORE) teams for 66 CBER and CDRH collaborative reviews by providing a unified clinical review supported by subspecialist oncologists, representing a 21% increase from FY2021. OCE's regulatory review supported at least 44 approvals of NDAs or BLAs (including supplements) as well clinical review of at least 26 Breakthrough requests.

Oncology Research and Development Projects

Project Optimus was launched in 2021 to reform the dose optimization and dose selection paradigm in oncology drug development. In FY2022, OCE published "The Drug-Dosing Conundrum in Oncology – When Less Is More.". Project Optimus partnered with Friends of Cancer Research (FOCR) and other key stakeholders to highlight potential strategies for dose optimization in a session titled, "Maximizing Benefit and Improving Tolerability for Patients through Dose Optimization," at the FOCR Annual meeting and published an accompanying white paper "Optimizing Dosing in Oncology Drug Development, additionally OCE led a workshop on "Getting the Dose Right: Optimizing Dose Election: Strategies in Oncology" at ASCO. In FY2022, OCE launched Project FrontRunner that concentrates on accelerated approvals in earlier disease settings. OCE established an internal working group and have had discussions with external stakeholders via Friends of Cancer Research to develop a white paper and will facilitate a public session at Friends of Cancer Research's annual meeting in November 2022. OCE research efforts focus 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. 12 new research awards in FY2022 focused on health equity and

special populations in oncology clinical trials; Immuno-oncology; Oncology Patient-focused Drug Development; Oncology Safety; Precision Oncology and Real-World Evidence.

Oncology Regulatory Programs

Under the Global and Regulatory Outreach Program, Project Orbis provides a framework for concurrent submission and review of oncology products among international partners. In FY2022, Project Orbis utilization rate for major FDA applications (new molecular entity and new indication submissions) was 40%. OCE held 47 teleconferences with international regulators and presented Project Orbis and other international efforts at 5 conferences.

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. In FY2022, Project Facilitate managed 607 Single patient INDs, for both emergency and non-emergency applications. FDA/OCE issued a draft guidance titled, "Real-Time Oncology Review (RTOR)". The purpose of this guidance is to provide recommendations to applicants on the process for submission of selected NDAs and BLAs with oncology indications for review under RTOR.

The OCE Patient-Focused Drug Development (PFDD) completed 93 product specific consultations and had 5 publications. Additionally, the program executed the annual Clinical Outcome Assessment in Cancer Clinical Trial public workshop with over 1100 registrants. PFDD continued to broaden collaborations in the field of patient-reported outcomes within the Agency, across governmental organizations, and international working groups

OCE Real World Evidence Program 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. OCE RWE Program includes partnerships with stakeholders throughout FDA Centers to ensure communication and consistency across cancer-specific submissions. RWE program supported oncology regulatory review, policy, and research with 97 consults, 22 external engagement presentations and 18 publications/abstracts.

Oncology Center of Excellence Health Equity

OCE Diversity in Oncology Program expanded external engagements and contributed significantly to Moonshot 2.0 goals. OCE led the development of draft guidance on "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Subgroups in Clinical Trials" that was published on April 13, 2022. OCE's Project Equity developed Standard Operating Procedures for reviewing diversity plans, provided training to approximately 125 oncology review and project management staff and established 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 25 presentations, roundtables, and symposia with a wide group of stakeholders from academia, professional organizations, non-profit organizations focused on cancer, patient advocacy policy groups, and pharmaceutical sponsors. In addition, Project Community is an OCE national initiative introducing the work of FDA oncologists and hematologists to people in the community, especially under- represented and underserved communities held 3 "Quarterly" Meetings (Listening Sessions) with Advocacy Groups from the Multiple Myeloma, Rare Cancers

and the Colorectal Cancer communities and developed corresponding cancer awareness educational materials available to the public. Project Community facilitated 12 public stakeholder engagements with posted recordings on topics such as "Eliminate the Gap: Addressing Cancer Disparities in the US Latinx LGBTQ+ Community" and "Cancer Moonshot: Community Conversations – Moving on Equity : OCE Expands Diversity Initiative," June 16-22, 2022, marked the second year of the OCE Project Community social media campaign #BlackFamCan initiated in accordance with Presidential Executive Order 13985, "Advancing Racial Equity and Support for Underserved Communities Through the Federal Government" and aligns with Cancer Moonshot 2.0. Project Community "National Black Family Cancer Awareness Week, had a 15-fold increase over last year's panel discussion YouTube views and a 101% increase in social media. OCE worked with Howard University Cancer Clinic (DC campus) and Enon Tabernacle Baptist Church (Philadelphia) to coordinate community-based #BlackFamCan public cancer screening events.

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 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (Output)	FY 2022: Developed 83 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participated in twelve 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

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
293206: Promote innovation and predictability in the development of safe and effective nanotechnology-based products by establishing scientific standards and evaluation frameworks to guide nanotechnology-related regulatory decisions. (Outcome)	FY 2022: 70 CORES projects with completed annual milestones Complete review of 100% of Medical Product nanotechnology standards (Target Met)	75 CORES projects with completed annual milestones Complete review of 100% of Medical Product nanotechnology standards	81 CORES projects with completed annual milestones Complete review of 100% of Medical Product nanotechnology standards	+6
291101: Percentage of scientists retained at FDA after completing Fellowship or Traineeship programs. (Outcome)	FY 2022: 23% Target: 20% (Target Exceeded)	20%	20%	Maintain
293205: Percentage of requests for combination product designations processed within the 60-day statutory requirement. (Output)	FY 2022: 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 2022: 132 Target: 125 (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 2022: 112 Target: 45 (Target Exceeded)	50	60	+10

Measure	Year and Most Recent Result / Target for Recent Result (Summary of Result)	FY 2023 Target	FY 2024 Target	FY 2024 +/- FY 2023
291406: Percentage of invoices issued on time within predefined dates in the month. (Output)	FY 2022: 100% Target: 98% (Target Exceeded)	98%	98%	Maintain

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

Nanotechnology

The Office of the Chief Scientist has added a new target to reflect the additional work this office does in reviewing Medical Product nanotechnology standards like ISO TC 229 and ASTM E56. Standards are an invaluable resource for industry and FDA staff. Effective and meaningful participation in standards development organizations (SDOs) for the products FDA regulates are critically important in the emerging area of nanotechnology. The use of standards can increase predictability, streamline premarket review, and facilitate market entry and use for safe and effective regulated products. For example, standards can help address certain aspects of the evaluation of nano medical products quality, safety and effectiveness, such as material specifications, testing methods, pass/fail performance criteria, and processes to address areas, such as risk management and usability.

Traineeship and Fellowship Programs

To support the Department's mission and FDA's scientific expertise, FDA is launching 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% in FY 2021 to reflect the new expanded program's expected baseline. Although the Traineeship program has not yet been fully implemented, and additional programs will come online over the next few years, FDA has met the initial target of 20% in FY 2022. FDA will continue to monitor and adjust the target for retention moving forward as necessary. For now, the target will remain at 20% in FY 2023 and 2024.

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 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
FDA White Oak Campus	**59,744**	**53,053**	**53,832**	**56,293**	**57,037**	**744**
Budget Authority	***45,913***	***45,914***	***46,664***	***48,414***	***53,124***	***4,710***
User Fees	***13,831***	***7,139***	***7,168***	***7,879***	***3,913***	***-3,966***
Other Rent and Rent Related	**119,877**	**146,293**	**153,062**	**164,550**	**173,845**	**9,295**
Budget Authority	***80,172***	***98,262***	***99,762***	***106,095***	***167,253***	***61,158***
User Fees	***39,705***	***48,031***	***53,300***	***58,455***	***6,592***	***-51,863***
GSA Rental Payments	**219,334**	**212,103**	**222,857**	**244,884**	**235,888**	**-8,996**
Budget Authority	***171,208***	***153,119***	***153,286***	***166,286***	***156,686***	***-9,600***
User Fees	***48,126***	***58,984***	***69,571***	***78,598***	***79,202***	***604***

Figure 63 – Infrastructure Funding History Table

The FY 2024 Budget request for the Infrastructure Program is $466,770,000, of which $377,063,000 is budget authority and $89,707,000 is user fees. At this level, the budget authority increases by $56,268,000 compared with the FY 2023 Enacted Budget, and user fees decrease by $55,225,000.

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 2024 Budget for GSA Rental Payments is $235,888,000, of which $156,686,000 is budget authority and $79,202,000 is user fees. The budget authority decreases by $9,600,000 compared with the FY 2023 Enacted Budget and user fees increase by $604,000.

The GSA-managed properties that provide office and laboratory space for FDA employees are essential facilities. The FY 2024 Budget for GSA Rental Payments covers the cost of rental payments to GSA for FDA's approximately more than 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 2024 Budget for Other Rent and Rent-Related is $173,845,000, of which $167,253,000 is budget authority and $6,592,000 is user fees. The budget authority proposes an increase of $61,158,000 compared with the FY 2023 Enacted Budget and user fees decrease by - $51,863,000.

The increase in budget authority reflected in the Budget 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 2024 Budget for White Oak is $57,037,000, of which $53,124,000 is budget authority and $3,913,000 is user fees. The budget authority proposes an increase of $4,710,000 compared with the FY 2023 Enacted Budget and user fees decrease by -$3,966,000.

The increase in budget authority in the Budget 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 2024 President's Budget: Infrastructure *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Enacted	**320,795**
FDA White Oak Complex	48,414
Other Rent and Rent Related	106,095
GSA Rental Payments	166,286
FY 2024 Budget Authority Changes	**3,400**
FDA White Oak Complex	626
Other Rent and Rent Related	12,374
GSA Rental Payments	(9,600)
Other Adjustments	**52,868**
FDARA Sec. 905 BA Shift	52,868
FDA White Oak Complex	4,084
Other Rent and Rent Related	48,784
FY 2024 Budget Net Total: Infrastructure	**377,063**

Figure 64 - Infrastructure Budget Authority

PROGRAM DESCRIPTION AND ACCOMPLISHMENTS

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. 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 headquarters White Oak Campus in Silver Spring, Maryland. Investing in FDA's facility objectives will provide the high-quality infrastructure and facilities needed for FDA employees to work to ensure FDA can achieve its 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 post-pandemic workplace flexibilities, FDA is developing a plan to further consolidate headquarters leased locations.

FDA is also collaborating 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 consolidation. The master plan is expected to be approved in the second quarter of FY 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 142,000 individuals in the U.S. in 2021
- 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 more than 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-owned or GSA-leased space are for headquarters facilities in the Maryland suburbs of Washington, D.C. FDA occupies GSA-owned or -leased space in approximately 273 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 when it acquires the space required to meet its mission in accordance with nationally recognized standards.

In FY 2022, 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 nine IMFs, enhance opioid interdiction efforts, and combat the addiction crisis threatening American families
- completed construction activities to expand CDER's laboratory in St. Louis, Missouri, that houses the Division of Pharmaceutical Analysis
- continued coordinating construction activities for a new leased CDER laboratory near the White Oak Campus to house a pilot plant for simulating the processing of drug substances and products manufacturing
- continued the renovation of an existing building to provide additional storage on the White Oak Campus to support FDA's expanding operations and growing workforce
- developed plans for and began implementing a space optimization initiative to take advantage of post-pandemic workplace flexibilities.

In FY 2023, FDA plans to:

- continue coordinating design activities and 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
- continue coordinating the 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 nine IMFs, enhance opioid interdiction efforts, and combat the addiction crisis threatening American families

- complete 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
- continue coordinating the renovation of an existing building to provide additional storage on the White Oak Campus to support FDA's expanding operations and growing workforce
- develop a space-optimization implementation plan based on post-pandemic workplace flexibilities.

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-managed 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-managed 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 11,300 as a result of occupying the last phase, two office and two lab buildings, in FY 2014 and instituting alternative office strategies, including increased telework.

By consolidating much of its headquarters workforce, FDA increased opportunities for staff to collaborate face-to-face, while reducing overall facility operating 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 post-pandemic workplace flexibilities, FDA is developing a plan to further consolidate headquarters GSA-leased locations.

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 65 – State-of-the-Art Laboratories at White Oak

Figure 66 – State-of-the-Art Laboratories at White Oak

Figure 67 – Anechoic Chambers Laboratory

Figure 68 – Nuclear Magnetic Resonance Laboratory Supporting CBER and CDER

Figure 69 – State-of-the-Art White Oak Infrastructure: Advanced Air Terminal Units Supporting Laboratories

Figure 70 – 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 move costs, alterations, and 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

BUDGET REQUEST

(Dollars in Thousands)	FY 2020 Actuals	FY 2021 Actuals	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	President's Budget (+/-) FY 2023 Enacted
Buildings and Facilities (Budget Authority)	43,289	11,091	12,788	12,788	18,788	6,000

Figure 71 – Buildings and Facilities Funding History Table

The FY 2024 OMBJ Budget Request is $18,788,000, a $6,000,000 increase compared to the FY 2023 Enacted Budget, consisting solely of budget authority.

FY 2024 President's Budget: Buildings and Facilities *Budget Authority - Dollars in Thousands*	
	Total
FY 2023 Enacted	**12,788**
FY 2024 Budget Authority Changes	**6,000**
FY 2024 Budget Net Total: B&F	**18,788**

Figure 72 - Buildings and Facilities Budget Authority

With these resources, 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.

At the Gulf Coast Seafood Laboratory facility, no projects are being planned in FY 2024 as we continue developing a project to relocate and improve operations.

At the Jefferson Labs Complex, FDA will initiate critical infrastructure projects to:

- Modify and update the Motor Control Center

- Provide fuel upgrades throughout the campus
- Renovate roofs

At the Muirkirk Road Complex, FDA will:

- Replace the flooring in outbuilding C3 for CVM
- Fund the design of the full laboratory renovation and consolidation of CVM laboratory operations in MOD2

At the Pacific Southwest Laboratory, FDA will:

- Replace the fire alarm system for the facility
- Add dedicated cooling systems to the LAN rooms in the facility
- Renovate Lab 1203

At the San Juan District Office and Laboratory, FDA will:

- Provide improvements to site lighting and fencing for the campus
- Upgrade the laboratory vacuum system
- Upgrade the fire alarm and sprinklers throughout the campus
- Address Building 1 settlement issues
- Upgrade HVAC monitoring across the campus

At the Winchester Engineering and Analytical Center, no projects are being planned in FY 2024 as we will have completed the consolidation of all buildings into the new replacement building in FY 2023.

The following table provides an allocation plan by site for use of the FY 2024 funds.

FY 2024 BUILDINGS AND FACILITIES ALLOCATION PLAN

BUILDINGS AND FACILITIES ALLOCATION PLAN FY 2024 Congressional Justification	
Site	**President's Budget**
CFSAN Gulf Coast Seafood Laboratory – Dauphin Island, AL	$0
Jefferson Laboratories Complex (NCTR & ORA Arkansas Lab) – Jefferson, AR	$8,000,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$6,350,000
ORA Pacific Laboratory SW – Irvine, CA	$2,488,000
San Juan District Office and Laboratory – San Juan, PR	$1,950,000
Winchester Engineering and Analytical Center – Winchester, MA	$0
B&F Project Total	**$18,788,000**

Figure 73 – Buildings and Facilities Allocation Plan

In FY 2024, 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 2024 will help reduce Scope 1, 2, and 3 greenhouse gas emissions by replacing or repairing aged, inefficient roofs and 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 facility objectives will provide the high-quality infrastructure and facilities needed for FDA employees to work 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, 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 77 existing FDA-owned facilities at six sites in the United States and Puerto Rico

Figure 74 – 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. The most recent facility condition assessments were completed in FY 2021.

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 2022 and Planned for FY 2023

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 2022, FDA investigated strategies for laboratory revitalization.

In FY 2023, FDA plans to develop a specific strategy for laboratory revitalization to include relocating certain laboratory operations.

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 2022, FDA:

- continued construction of the 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 renovation of roofs on several buildings
- designed roof renovations for buildings 26 and 60
- designed the renovation of Building 62
- completed the design for a critical Pathology lab
- completed the design for Building 53E
- completed the design for a new Operations and Maintenance building (Building 43)
- completed the design and installation of a renovated campus fire-alarm system

- constructed exterior lighting upgrades
- designed Building 26 exterior upgrades
- designed Water Tower upgrades
- designed Guard Station upgrades.

In FY 2023, 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.

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 2022, FDA:

- completed coordinating the design for replacement of the substation housing, switchgear, and electrical feeders on campus and began construction
- continued construction of the projects for replacement of generators and correcting the main laboratory AHUs
- completed construction of eyewash stations in select MOD2 research buildings to correct safety deficiencies
- initiated a project for design of a hot-water system to resolve issues with MOD2 animal-research buildings
- completed the project to prepare a program of requirements and building assessment for MOD1 and MOD2 laboratory buildings to meet multiple program requirements
- developed a round-robin strategy that will serve as the basis of design for renovation of the MOD2 laboratories
- completed the design and began construction to provide a new backflow preventer for the entire campus
- initiated a project to add exhaust fans to Building E and an air-conditioning unit to Building F
- completed design and began construction for upgrade and renovation of the aquaculture facility (Building H)

- continued coordinating an update of the campus master plan.

In FY 2023, FDA plans to:

- complete the update of the campus master plan.
- 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 upgrade the HVAC system in outbuildings E &F

Pacific Southwest Laboratory – Irvine, California

The Pacific Southwest Laboratory provides analytical laboratory support to FDA's regulatory mission in the Pacific Region.

In FY 2022, FDA:

- continued construction of HVAC system and controls improvements
- initiated a project to design and upgrade the HVAC systems in the LAN closets to support additional IT equipment
- continued to study exterior wall cracks
- continued a construction project addressing interior cracks in the building
- initiated construction of a nitrogen-system upgrade
- completed the design of replacement cooling towers and controls.

In FY 2023, FDA plans to:

- remediate exterior wall cracking and complete remediation of interior wall cracking
- replace the vacuum-pump system for the facility that is beyond 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 2022, FDA initiated construction activities for the new office building addition for the District Office funded with both B&F and Non-recurring Expenses Fund (NEF) resources.

In FY 2023, FDA plans to:

- continue construction of the office building addition
- replace five rooftop HVAC units and supply and return ducts in Building 1.

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.

FDA is in the process of executing a design-build NEF project to replace the existing WEAC facilities with a new laboratory building on the same site.

In FY 2022, FDA continued construction of the new laboratory.

In FY 2023, FDA plans to supplement the project with B&F funds to complete construction of the new laboratory.

PROGRAM ACTIVITY DATA

Program Activity Data

Facility	FY 2022 Estimate	FY 2023 Estimate	FY 2024 Estimate
CFSAN Gulf Coast Seafood Laboratory	81	81	80
Jefferson Laboratories Complex	68	70	79
Muirkirk Road Complex	62	64	65
ORA Pacific Southwest Laboratory	94	94	96
San Juan District Office and Laboratory	62	62	70
Winchester Engineering And Analytical Center	99	99	99

Figure 75 – Program Activity Data

NONRECURRING EXPENSES FUND

BUDGET SUMMARY

(Dollars in Thousands)

	FY 2022[116]	FY 2023[117]	FY 2024[118]
Notification[119]	$81,200	$109,070	$62,600

Figure 76 – Budget Summary

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. With the exception of 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 2024

FDA received $62.6 million from FY 2024 NEF for the following projects:

Facilities projects:
Jefferson Laboratory Complex, Building 53E Renovation, – Building 53E currently houses old research labs and offices for research staff. Exterior and interior systems and finishes have reached their useful life and a renovation is needed to modernize the building to include improving energy efficiency and compliance with ADA requirements. This follows the Jefferson Lab Complex (JLC) masterplan for Building 53.

Pacific Northwest Laboratory Infrastructure, – The existing laboratory heating, ventilating, and air conditioning systems and controls and other building mechanical and electrical infrastructure systems are antiquated and unreliable. They often compromise laboratory pressurization, which poses a health and safety threat to staff in the building, especially the scientists that directly work

[116] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on October 22, 2021.

[117] Notification submitted to the Committees on Appropriations in the House of Representatives and the Senate on June 17, 2022.

[118] HHS has not yet notified for FY 2024.

[119] Pursuant to Section 223 of Division G of the Consolidated Appropriation Act, 2008, notification is required of planned use.

in the laboratories. Note: This project would be a temporary (6-8 years) measure to allow safe and more reliable operations until long-term plans for the building (i.e., significant renovation with an addition or complete relocation of the lab) can be developed and implemented.

Jefferson Laboratory Complex Water Tower, – The JLC is not served by a public water system and instead the domestic water system consists of a well, treatments systems and three water towers. The towers are filled with treated well water and then tie into a main system which supplies the water across the entire campus for all campus operations, including drinking water. This project will replace these aged towers to modernize them with current safety features and ensure compliance with state drinking water standards.

Jefferson Laboratory Complex Buildings 44 and 45T, – Building 45T is a quadruple modular office trailer that currently houses offices, restrooms, storage closets and a computer lab and is occupied by operations and maintenance staff. This building has exceeded its useful life and needs to be replaced. The current office trailers are not energy efficient, contain mold and are starting to show signs of failure creating an unsafe working environment. Building 44 houses the electrical shop and is in need of repairs and renovation to provide acceptable space for the function. This project will replace the 45T trailer with a permanent building and make the necessary repairs and renovations to Building 44.

Jefferson Laboratory Complex, Replace Air Handlers, – Buildings 26 and 53 are critical laboratory/research buildings that support FDA regulatory science and research at JLC. The air handling units (AHUs) and exhaust fans that serve these buildings are well past their useful life and are currently at risk of failing, which would result in a lengthy shutdown, lost research and delayed regulatory analyses. This project will replace these AHU and exhaust fans.

IT projects:
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 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 as outlined in the Office of Management and Budget (OMB) Memorandum 21-07, 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

In FY 2023, FDA received $109.1 million in resources to for the following projects:

Muirkirk Road Complex, Laboratory Renovation and Office Building, $21.5 million – 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 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.

Infrastructure Improvements – Steam Boiler, Cooling Tower, Chiller and Generator Replacement, Pacific Southwest Laboratory, Irvine, CA, $15.0 million – renovation of these infrastructure systems and the addition of a steam boiler will provide the lab and office space with properly functioning building systems that are fully redundant in operation, so that the vital work performed in this facility can continue without interruption.

CFSAN Renovation of Wiley Building 3rd and 4th Floor Labs, College Park, MD, $8.8 million – to create state-of-the-art microbiology and sequencing laboratories with more flexible spaces that can easily be reconfigured to accommodate current and future laboratory tasks and operations. The renovation plan will also include important safety measures to ensure there is a common entry/exit area where scientists will put on or take off their personal protective equipment and wash their hands before entering or exiting the labs.

Replace Six AHUs and Exhaust Fans, Pacific Southwest Laboratory, Irvine, CA, 18.8 million – The existing building's AHUs and exhaust fans have aged beyond their useful lives and are unreliable. The proposed renovation of these infrastructure systems will provide the lab and office space with properly functioning building systems, so that the vital work performed in this facility can continue without interruption.

Modifications to Aquaculture Building, Muirkirk Road Complex, Laurel, MD, $2.4 million – to revitalize the aged, existing aquaculture facility to better support CVM's research now and in the future.

Jefferson Labs Complex, Data Recovery Center, $22.00 million – FDA will construct a Disaster Recovery Center on its FDA-owned Complex in Arkansas that will accommodate FDA-wide Information Technology disaster-recovery equipment and operations that are necessary to protect FDA operations. The project is part of FDA's data center consolidation plan and will also allow the relocation of the National Center for Toxicological Research Data Center to address critical reliability concerns, replace equipment and systems that are past their useful lives, and ensure the constructability of the JLC Master Plan.

Jefferson Labs Complex, Pathology Lab Fit Out, $20.6 million – FDA will relocate, consolidate, and modernize pathology operations on its FDA-owned Complex in keeping with the JLC Master Plan. Relocating the pathology suite will consolidate operations for efficiency and provide cutting-edge labs and storage for the program.

BUDGET ALLOCATION FY 2022

In FY 2022, FDA received $81.2 million in resources for the following projects:

Jefferson Labs Complex, $38.7 million – for the construction of a new central chiller plant to replace two separate, functionally obsolete chiller plants in accordance with the campus master plan.

Denver Laboratory, $42.5 million – supplemental funding required to address changing market conditions for replacing the existing laboratory in an aged and functionally obsolete GSA-owned building with a new, flexible, modern GSA-owned laboratory building.

BUDGET ALLOCATION FY 2021 AND PRIOR

From FY 2015 through FY 2021, FDA received a total of $311.5 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 Office of Regulatory Affairs' (ORA) 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 the National Center for Toxicological Research (NCTR) located at FDA's owned JLC, 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 provided the resources needed to construct a new office building addition at FDA's 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.

SUPPLEMENTARY ITEMS

OBJECT CLASS TABLES

BUDGET AUTHORITY BY OBJECT CLASS

(Dollars in Thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 PB +/- FY 2023 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,008,112	1,075,781	1,187,127	111,346
Other than full-time permanent (11.3)	71,834	76,656	84,590	7,934
Other personnel compensation (11.5)	44,597	47,590	52,516	4,926
Military Personnel - Basic Allowance for Housing (11.6)	167	178	197	18
Military personnel (11.7)	84,405	90,070	99,393	9,322
Special personnel services payments (11.8)	1,240	1,323	1,460	137
Subtotal, Personnel Compensation	**1,210,354**	**1,291,599**	**1,425,283**	**133,684**
Benefits:				
Civilian benefits (12.1)	421,595	449,894	496,459	46,565
Military benefits (12.2)	8,893	9,490	10,473	982
Benefits to former personnel (13.0)	2	2	2	
Subtotal, Benefits	**430,490**	**459,387**	**506,934**	**47,548**
Total Personnel Compensation and Benefits	**1,640,844**	**1,750,986**	**1,932,217**	**181,231**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	22,867	24,362	27,273	2,911
Transportation of things (22.0)	3,244	3,457	3,870	413
Rental payments to GSA (23.1)	153,286	166,286	156,686	-9,600
Rent payments to others (23.2)	555	592	662	71
Communication, utilities, and misc. charges (23.3)	20,943	22,313	24,979	2,666
Printing and reproduction (24.0)	1,210	1,290	1,444	154
Subtotal, Contractual Services	**202,106**	**218,299**	**214,914**	**-3,384**
Other Contractual Services:				
Consulting services (25.1)	59,432	63,319	70,886	7,567
Other services (25.2)	353,493	376,612	421,618	45,006
Purchase of goods and svcs from Govt Acts. (25.3)	519,140	553,093	619,189	66,096
Operation and maintenance of facilities (25.4)	83,099	88,534	99,114	10,580
Research and Development Contracts (25.5)	75,849	80,810	90,466	9,657
Medical care (25.6)	18,048	19,228	21,526	2,298
Operation and maintenance of equipment (25.7)	58,756	62,599	70,080	7,481
Subtotal, Other Contractual Services	**1,167,817**	**1,244,194**	**1,392,879**	**148,685**
Supplies and Materials:				
Supplies and materials (26.0)	52,204	55,619	62,265	6,647
Equipment (31.0)	42,572	45,356	50,776	5,420
Land and Structures (32.0)	38,880	41,423	46,373	4,950
Grants, subsidies, and contributions (41.0)	221,457	235,941	264,136	28,196
Insurance claims and indemnities (42.0)	1,052	1,121	1,255	134
Interest and dividends , Refunds (43.0, 44.0)				
Receivables-collected (61.7)				
Subtotal, Supplies and Materials	**356,166**	**379,459**	**424,806**	**45,346**
Total Contractual Services and Supplies	**1,726,089**	**1,841,952**	**2,032,599**	**190,647**
Total Budget Authority by Object Class	**3,366,933**	**3,592,938**	**3,964,816**	**371,878**

Figure 77 - Budget Authority by Object Class

USER FEES BY OBJECT CLASS

(Dollars in Thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 PB +/- FY 2023 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	889,368	964,457	1,010,554	46,097
Other than full-time permanent (11.3)	90,086	97,692	102,361	4,669
Other personnel compensation (11.5)	76,872	83,362	87,346	3,984
Military Personnel - Basic Allowance for Housing (11.6)	7	7	8	
Military personnel (11.7)	72,991	79,154	82,937	3,783
Special personnel services payments (11.8)	202	219	230	10
Subtotal, Personnel Compensation	**1,129,525**	**1,224,891**	**1,283,435**	**58,544**
Benefits:				
Civilian benefits (12.1)	383,824	416,230	436,124	19,894
Military benefits (12.2)	11,284	12,237	12,822	585
Benefits to former personnel (13.0)	---	---	---	---
Subtotal, Benefits	**395,108**	**428,467**	**448,945**	**20,479**
Total Personnel Compensation and Benefits	**1,524,633**	**1,653,357**	**1,732,380**	**79,023**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	24,852	27,048	28,365	1,317
Transportation of things (22.0)	1,255	1,365	1,432	66
Rental payments to GSA (23.1)	69,892	70,764	72,876	2,112
Rent payments to others (23.2)	9	10	10	
Communication, utilities, and misc. charges (23.3)	1,913	2,082	2,183	101
Printing and reproduction (24.0)	554	603	632	29
Subtotal, Contractual Services	**98,475**	**101,872**	**105,499**	**3,627**
Other Contractual Services:				
Consulting services (25.1)	107,021	116,474	122,146	5,672
Other services (25.2)	399,659	434,960	456,142	21,183
Purchase of goods and svcs from Govt Acts. (25.3)	466,212	507,391	532,101	24,710
Operation and maintenance of facilities (25.4)	37,399	40,702	42,684	1,982
Research and Development Contracts (25.5)	47,440	51,630	54,144	2,514
Medical Care (25.6)	16,914	18,408	19,304	896
Operation and maintenance of equipment (25.7)	30,997	33,735	35,378	1,643
Subtotal, Other Contractual Services	**1,105,643**	**1,203,300**	**1,261,901**	**58,601**
Supplies and Materials:				
Supplies and materials (26.0)	18,909	20,579	21,581	1,002
Equipment (31.0)	3,807	4,144	4,345	202
Land and Structures (32.0)	408	444	466	22
Grants, subsidies, and contributions (41.0)	100,219	109,071	114,383	5,312
Insurance claims and indemnities (42.0)	61	67	70	3
Interest and dividends , Refunds (43.0, 44.0)	32,851	35,753	37,494	1,741
Receivables-collected (61.7)	41	45	47	2
Subtotal, Supplies and Materials	**156,298**	**170,103**	**178,387**	**8,284**
Total Contractual Services and Supplies	**1,360,415**	**1,475,275**	**1,545,787**	**70,512**
Total User Fees by Object Class	**2,885,048**	**3,128,632**	**3,278,167**	**149,535**

Figure 78 - User Fee by Object Class

PROGRAM LEVEL BY OBJECT CLASS

(Dollars in Thousands)	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 PB +/- FY 2023 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,897,479	2,040,238	2,197,681	157,443
Other than full-time permanent (11.3)	161,920	174,348	186,951	12,603
Military Personnel - Basic Allowance for Housing (11.6)	121,468	130,952	139,862	8,910
Other personnel compensation (11.5)	174	185	204	19
Military personnel (11.7)	157,396	169,224	182,330	13,106
Special personnel services payments (11.8)	1,442	1,543	1,690	147
Subtotal, Personnel Compensation	**2,339,879**	**2,516,490**	**2,708,718**	**192,228**
Benefits:				
Civilian benefits (12.1)	805,418	866,124	932,583	66,459
Military benefits (12.2)	20,178	21,727	23,294	1,567
Benefits to former personnel (13.0)	2	2	2	
Subtotal, Benefits	**825,598**	**887,853**	**955,880**	**68,027**
Total Personnel Compensation and Benefits	**3,165,477**	**3,404,343**	**3,664,598**	**260,255**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	47,719	51,410	55,638	4,229
Transportation of things (22.0)	4,499	4,822	5,302	480
Rental payments to GSA (23.1)	223,178	237,050	229,562	-7,488
Rent payments to others (23.2)	564	602	673	71
Communication, utilities, and misc. charges (23.3)	22,856	24,395	27,163	2,768
Printing and reproduction (24.0)	1,764	1,892	2,076	183
Subtotal, Contractual Services	**300,581**	**320,170**	**320,413**	**243**
Other Contractual Services:				
Consulting services (25.1)	166,453	179,793	193,032	13,239
Other services (25.2)	753,152	811,572	877,761	66,189
Purchase of goods and svcs from Govt Acts. (25.3)	985,353	1,060,484	1,151,290	90,806
Operation and maintenance of facilities (25.4)	120,498	129,236	141,798	12,562
Research and Development Contracts (25.5)	123,289	132,440	144,611	12,171
Medical care (25.6)	34,962	37,636	40,830	3,194
Operation and maintenance of equipment (25.7)	89,753	96,334	105,458	9,124
Subtotal, Other Contractual Services	**2,273,460**	**2,447,495**	**2,654,780**	**207,285**
Supplies and Materials:				
Supplies and materials (26.0)	71,114	76,198	83,847	7,649
Equipment (31.0)	46,379	49,499	55,121	5,622
Land and Structures (32.0)	39,288	41,867	46,839	4,972
Grants, subsidies, and contributions (41.0)	321,676	345,012	378,519	33,507
Insurance claims and indemnities (42.0)	1,113	1,188	1,325	137
Interest and dividends , Refunds (43.0, 44.0)	32,851	35,753	37,494	1,741
Receivables-collected (61.7)	41	45	47	2
Subtotal, Supplies and Materials	**512,463**	**549,562**	**603,193**	**53,630**
Total Contractual Services and Supplies	**3,086,504**	**3,317,227**	**3,578,385**	**261,158**
Total Program Level by Object Class	**6,251,981**	**6,721,570**	**7,242,983**	**521,413**

Figure 79 - Total Program Level by Object Class

SALARIES AND EXPENSES TABLE

	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 PB +/- FY 2023 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,008,112	1,075,781	1,187,127	111,346
Other than full-time permanent (11.3)	71,834	76,656	84,590	7,934
Other personnel compensation (11.5)	44,597	47,590	52,516	4,926
Military personnel (11.7)	84,405	90,070	99,393	9,322
Special personnel services payments (11.8)	1,240	1,323	1,460	137
Subtotal, Personnel Compensation	**1,210,187**	**1,291,421**	**1,425,086**	**133,665**
Benefits:				
Civilian benefits (12.1)	421,595	449,894	496,459	46,565
Military benefits (12.2)	8,893	9,490	10,473	982
Benefits to former personnel (13.0)	2	2	2	0
Subtotal, Benefits	**430,490**	**459,387**	**506,934**	**47,548**
Total Pay Costs	**1,640,677**	**1,750,808**	**1,932,020**	**181,213**
Travel and transportation of persons (21.0)	22,867	24,362	27,273	2,911
Transportation of things (22.0)	3,244	3,457	3,870	413
Rental payments to GSA (23.1)	153,286	166,286	156,686	-9,600
Rent payments to others (23.2)	555	592	662	71
Communication, utilities, and misc. charges (23.3)	20,943	22,313	24,979	2,666
Printing and reproduction (24.0)	1210	1290	1444	154
Subtotal, Contractual Services	**202,106**	**218,299**	**214,914**	**-3,384**
Other Contractual Services:				
Advisory and assistance services (25.1)	59,432	63,319	70,886	7,567
Other services (25.2)	353,493	376,612	421,618	45,006
Purchase of goods and svcs from Govt Acts. (25.3)	519,140	553,093	619,189	66,096
Operation and maintenance of facilities (25.4)	83,099	88,534	99,114	10,580
Research and Development Contracts (25.5)	75,849	80,810	90,466	9,657
Operation and maintenance of equipment (25.7)	58,756	62,599	70,080	7,481
Subtotal, Other Contractual Services	**1,149,770**	**1,224,966**	**1,371,353**	**146,387**
Supplies and materials (26.0)	52,204	55,619	62,265	6,647
Total Non-Pay Costs	**1,404,080**	**1,498,884**	**1,648,533**	**149,649**
Total Salary and Expense	**3,044,757**	**3,249,691**	**3,580,553**	**330,862**
Direct FTE	**10,175**	**10,353**	**10,762**	**409**

Figure 80 - Salaries and Expenses Table

DETAIL OF FULL-TIME EQUIVALENTS

	FY 2022 Actuals			FY 2023 Enacted			FY 2024 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Center for Food Safety and Applied Nutrition	1,126	39	1,165	1,188	39	1,227	1,323	39	1,362
Center for Drug Evaluation and Research	5,149	471	5,620	5,267	471	5,738	5,288	471	5,759
Center for Biologics Evaluation and Research	1,257	48	1,305	1,177	48	1,225	1,181	48	1,229
Center for Veterinary Medicine	716	10	726	729	10	739	790	10	800
Center for Devices and Radiological Health	1,865	66	1,931	1,935	66	2,001	1,995	66	2,061
National Center for Toxicological Research	317	1	318	285	1	286	285	1	286
Office of Regulatory Affairs	4,748	338	5,086	4,658	338	4,996	4,729	338	5,067
Headquarters and Office of the Commissioner	937	58	995	905	58	963	1,014	58	1,072
Export Certification	19	---	19	26	---	26	26	---	26
Color Certification	36	---	36	37	---	37	37	---	37
Family Smoking Prevention and Tobacco Control Act.	1,125	46	1,171	1,172	46	1,218	1,173	46	1,219
Priority Review Vouchers (PRV) Pediatric Disease	18		18	11		11	11	---	11
21st Century Cures (BA Only)	83		83	187		187	187	---	187
Cancer Moonshot (BA Only)			---			---	---	---	---
Total	**17,397**	**1,077**	**18,474**	**17,577**	**1,077**	**18,654**	**18,039**	**1,077**	**19,116**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2018	13
FY 2019	13
FY 2020	13
FY 2021	13
FY 2022	13

* FTE figures do not include an estimated 82 reimbursable, 2 FOIA, 47 PEPFAR, 1 IDDA, and 129 COVID Supplemental.

Figure 81 - Detail of Full-Time Equivalents

DETAIL OF POSITIONS

	FY 2022 Final	FY 2023 Enacted	FY 2024 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	41	42	43
Total Executive Service	**41**	**42**	**43**
Total - ES Salary	**$8,413,692**	**$8,981,295**	**$9,484,561**
General Schedule (GS)			
GS-15	1,122	1,145	1,175
GS-14	3,489	3,559	3,652
GS-13	4,417	4,506	4,624
GS-12	1,843	1,880	1,929
GS-11	642	655	673
GS-10	5	5	5
GS-9	304	310	318
GS-8	26	27	27
GS-7	218	223	229
GS-6	19	19	19
GS-5	21	22	22
GS-4	14	14	14
GS-3	3	3	4
GS-2	3	3	4
GS-1	2	2	2
Total General Schedule	**12,128**	**12,372**	**12,698**
Total - GS Salary	**$1,444,517,159**	**$1,484,660,777**	**$1,554,538,722**
Administrative Law Judges (AL)	---	---	---
Scientific/Senior Level (ST/SL)	2	2	2
Senior Biomedical Research Service (RS)	47	48	50
Scientific Staff Fellows (RG) (Title 42)	779	794	815
Distinguished Consultants/Senior Science Managers (RF) (Title 42)	95	97	99
Former Performance Mgmt Recognition System Employees (GM)	---	---	---
Physicians and Dentists - (GP) (Title 38)	473	483	495
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]	2,120	2,163	2,220
Wage Grade	8	9	9
Consultants[2]	1,535	1,566	1,607
Total FTE (End of Year)[1]	**18,307**	**18,654**	**19,116**
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 82 - Detail of Positions

IDEA DIGITAL MODERNIZATION ACT

Modernization of the Public-Facing Digital Services – 21st Century Integrated Digital Experience Act

The 21st Century Integrated Digital Experience Act (IDEA) was signed into law on Dec. 20, 2018. It requires data-driven, user-centric website and digital services modernization, website consolidation, and website design consistency in all Executive Agencies. Departments across the federal landscape are working to implement innovative digital communications approaches to increase efficiency and create more effective relationships with their intended audiences. The American public expects instant and impactful communications – desired, trusted content available when they want it, where they want it, and in the format they want it. If the consumer is not satisfied they move on and our opportunity for impact is lost.

Modernization Efforts

In FY 2019 HHS engaged Department leadership and developed a Digital Communications Strategy that aligns with the requirements of IDEA. In FY 20, HHS Digital Communications Leaders began implementation of the Strategy in alignment with IDEA, beginning to align budgets to modernization requirements.

As the result of a comprehensive review of costs associated with website development, maintenance, and their measures of effectiveness, HHS will prioritize:

- modernization needs of websites, including providing unique digital communications services, and
- continue developing estimated costs and impact measures for achieving IDEA.

Over the next four years HHS will continue to implement IDEA by focusing extensively on a user-centric, Digital First approach to both external and internal communications and developing performance standards. HHS will focus on training, hiring, and tools that drive the communication culture change necessary to successfully implement IDEA.

Over the next year, HHS Agencies and Offices will work together to continue to implement IDEA and the HHS Digital Communications Strategy across all communications products and platforms.

CYBERSECURITY FUNDING

Resources for Cyber Activities
Food and Drug Administration

(Dollars in millions)

Cyber Category	FY 2022 Final	FY 2023 Enacted	FY 2024 President's Budget	FY 2024 +/- FY 2023
Cyber Human Capital	--	--	--	--
Sector Risk Management Agency (SRMA)	--	--	--	--
Securing Infrastructure Investments	--	--	--	--
Other NIST CSF Capabilities:				
Detect	16.410	17.670	20.340	+2.670
Identity	24.790	23.760	25.210	+1.450
Protect	10.870	10.260	11.370	+1.110
Recover	4.720	4.940	5.040	+0.100
Respond	1.000	1.000	1.000	--
Total Cyber Request	**57.790**	**57.630**	**62.960**	**5.330**
Technology Ecosystems (non-add)	--	--	--	--
Zero Trust Implementation (non-add)	*57.790*	*57.630*	*62.960*	*5.330*

Figure 83 – Cybersecurity Funding Table

SIGNIFICANT ITEMS

APPROPRIATIONS COMMITTEES SIGNIFICANT ITEMS

JOINT EXPLANATORY STATEMENT

1. Aging Treatments

The agreement urges the FDA to develop clearer regulatory pathways for emerging aging treatments and to provide an update on its progress in the fiscal year 2024 congressional budget justification. The agreement also urges the FDA to increase support for regulatory science that can inform these pathways, including collaborations with the National Institutes of Health, industry, and academia on the discovery and validation of biomarkers.

FDA Response:

The Agency appreciates and shares Congress' interest in the field of geroscience and the development of therapeutics in this emerging field. The Agency has a robust program, has provided guidance to support the development of new biomarkers, and works with the National Institutes of Health (NIH), industry, and academia, often through public-private partnerships such as the Critical Path Institute, to support biomarker identification and development, including potential surrogate endpoints.

In May 2022, FDA and the Duke-Margolis Center for Health Policy convened a virtual public workshop on Translational Science in Drug Development: Surrogate Endpoints, Biomarkers and More. The goal was to present best practices and use cases for successfully bringing forward evidence generated through translational science for regulatory submissions. While not specific to geroscience, the workshop presented efforts from FDA, NIH, academia, patient groups, and industry to support surrogate endpoint and other biomarker identification and development for use in therapeutic development and regulatory submissions that could be applicable to identifying novel biomarkers and endpoints for potential geroscience therapeutics. For example, one session specifically focused on the scientific considerations for identification and development of novel surrogate endpoints for use in clinical development programs. These types of engagements foster interaction and discussion among stakeholders who are developing these tools and provide researchers and sponsors insight into the scientific considerations that FDA will take into account when evaluating novel biomarkers and translational science approaches.

HOUSE REPORT (117-392)

1. Advertising Expenditures

Advertising Expenditures.—The Committee believes that, as the largest advertiser in the United States, the federal government should work to ensure fair access to its advertising contracts for small, disadvantaged businesses and businesses owned by minorities and women. The Committee directs each department and agency to include the following information in its fiscal year 2024 budget justification: expenditures for fiscal year 2022 and expected expenditures for fiscal years 2023 and 2024 for (1) all contracts for advertising services; and (2) contracts for the advertising services of socially and economically disadvantaged small businesses concerns (as defined in section 8(a)(4) of the Small Business Act (15 U.S.C. 637 (a)(4)); and women- and minority-owned businesses.

FDA Response:

FDA advertising obligations for fiscal year (FY) 2022 are represented in the table below. As of November 29, 2022, no contracts for advertising services have been awarded to date for FY 2023, and projections are not available for FY 2024.

The Center for Tobacco Products (CTP) plans to continue robust investments in public education campaigns in FY 2023 and FY 2024. The FY 2022 award was made in September 2022, and the FY 2023 award has an anticipated award timing of September 2023. The contract for the CTP public education campaigns includes a small business contracting plan stipulating that 33% of labor expenditures be subcontracted to small, disadvantaged, and women and minority-owned businesses. Annual, fiscal year reporting on small business subcontracting is a contract requirement. Non-labor contract expenditures primarily purchase advertising space on digital media properties that effectively reach teenagers nationwide with tobacco product use prevention messaging (i.e., YouTube, Instagram, Spotify, Twitch, etc.).

FDA recognizes that increasing contract opportunities for small disadvantaged and women-owned small businesses is a top priority for the Administration and is committed to doing all that it can to increase these opportunities where possible. The Agency also notes its successes in small business contracting overall. In FY 2022, FDA exceeded the U.S. Department of Health and Human Services (HHS) small business goal of 22.85% by awarding 33.4% of its obligations to small businesses. FDA exceeded the HHS small disadvantaged business (SDB) goal of 13.08% by awarding 23.95% of its obligations to SDBs. FDA also awarded 11% of its obligations to women-owned small businesses, exceeding the Department's 5% goal. FDA is committed to continuing to work with small businesses.

Advertising Services Contracts	FY 2022 Obligations
Contracts for advertising services (Product Service Code R701; Advertising) Contract for CTP Public Education Campaign (Product Service Code R426; Communications)	$287,707* $154,660,000
Contracts for socially and economically disadvantaged small businesses concerns/ Contracts for women and minority owned businesses (non-add) R701	$0*

Figure 84: FY 2022 Service Contracts Obligations

*Note: Outside CTP's public education campaigns, FDA's largest contract for advertising services in FY 2022 was an award worth $250,000 for the FDA Recruitment Campaign. This award was made to the only vendor authorized by the Washington Metropolitan Area Transit Authority (WMATA) to provide advertising services on WMATA buses and trains. Accordingly, FDA could not make those funds available to small disadvantaged or women-owned small businesses.

2. Conditions of Employment

Conditions of Employment.—The Committee recognizes that harassment, including sexual harassment and assault, continues to be pervasive in the workplace, and that the use of pre-dispute nondisclosure and non-disparagement clauses as conditions of employment can perpetuate illegal conduct by silencing survivors and shielding perpetrators. The Committee directs USDA, FDA and CFTC to assess the number of pre-dispute nondisclosure and nondisparagement clauses in employment contracts used by contractors receiving Federal funds from those agencies, the estimated dollar value of those contracts, and to include a report with their findings in their fiscal year 2024 budget request.

FDA Response:

The Administration strongly supports the Speak Out Act (P.L. 117-224), signed into law on December 7, 2022. This bipartisan legislation will prohibit the enforcement of nondisclosure agreements (NDAs) and nondisparagement clauses between employers and employees and independent contractors, and between goods and services providers and consumers, that were in place before a sexual assault or harassment dispute, enabling survivors to speak out about workplace sexual assault and harassment. The Administration looks forward to continuing to work with the Congress to advance broader legislation that addresses the range of issues implicated in NDAs and nondisparagement clauses, including those related to discrimination on the basis of race, unfair labor practices, and other violations.

FDA contracts to procure goods and services are governed by the Federal Acquisition Regulations (FAR), Health and Human Services Acquisition Regulations (HHSAR), and local clauses, which dictate the acquisition and award process, structure, format and, in large part, the contents of all contracts. Currently there is neither statutory nor regulatory authority requiring contract terms or conditions regarding these types of NDAs and nondisparagement clauses in federal contracts. Given the absence of statutory authority to dictate these terms, FDA does not include language in contracts for goods or services concerning NDAs and nondisparagement clauses in employment contracts between individual vendors and their individual employees. FDA's contracts create no obligation on the part of vendors under contract to report any language or agreements that they have in place. A voluntary information collection from vendors under these conditions would create a data set that is incomplete and unreliable. FDA would need statutory authority to require acknowledgment by potential vendors that they are precluded from including such language in their employment contracts, as a requirement of doing business with the federal government. Without that statutory authority, FDA cannot impose such a requirement or provide the requested information in a meaningful, timely, or accurate manner.

3. Non-Human Primates

Non-Human Primates.—The Committee continues to encourage the FDA to reduce primate testing, prioritize alternative research methods to relocate primates to sanctuaries and requests that a progress report continue to be included in the FDA's annual budget justification.

FDA Response:

FDA takes seriously its charge for the appropriate welfare of research animals in our care and is deeply committed to ensuring the responsible and humane care of animals, including adhering to the important principles of replacing, reducing, and refining animal studies (the 3Rs). In many instances, nonhuman primates (NHPs) are the only relevant animal species for addressing critical regulatory scientific research questions. This is because NHPs are evolutionarily closer to humans than other laboratory animals and share many similarities with humans in immunology, reproduction, development, neuroanatomical organization, and cognitive capabilities.

FDA continues to utilize its internal standard guideline on the placement of research animals. The guideline describes the policy, procedures, and eligibility criteria for the transfer, adoption, retirement, or other handling of FDA-owned research animals. Consistent with this internal guideline, effective in November 2019 and most recently revised in December 2022, FDA has continued to advance intergovernmental collaborations and transfers to other research programs, as deemed appropriate. This approach is preferred to retirement to further research capacity and reduce the number of NHPs entering research, as well as to help mitigate challenges related to the constrained supply of NHPs which has arisen in part as a consequence of the current COVID-19 pandemic.

In 2022, FDA continued its active participation and sponsorship with the National Academies of Sciences, Engineering, and Medicine's (NASEM) Board on Animal Health Sciences, Conservation, and Research Institute (BAHSCR, formerly known as the Institute for Laboratory Animal Research). To provide additional perspectives, FDA also participated and presented in a workshop convened by NASEM, Nonhuman Primate Model Systems: State of the Science and Future Needs.

As a broader Agency initiative, the FY 2023 President's Budget request included $5.0 million in new funding to implement an FDA-wide New Alternative Methods Program to spur the adoption of new alternative methods for regulatory use that can replace, reduce, and refine animal testing and improve predictivity of nonclinical testing to streamline the development of FDA-regulated products and help bring them to the U.S. public and patients more rapidly and more efficiently while assuring they are safe, effective, and that patients can depend on them. FDA appreciates that Congress provided this additional funding in FY 2023. With dedicated funding for alternative methods, FDA will begin to implement a program with staff who are focused on alternative methods to evaluate the suitability and validity of these methods to best inform the Agency's regulatory decision-making process. It has long been our position that any non-animal method needs to be backed by science and provide information at least as useful as the animal method it replaces. This standard is critical for the Agency to uphold its obligation to protect public health. FDA presented this proposed program to the Science Board to the Food and Drug Administration at its June 2022 meeting ; that presentation included examples of new alternative methods applied research at FDA.

We recognize that this overarching effort also may provide opportunities for future intramural research conducted or supported by the Agency. We are assessing current FDA alternative methods activities to identify the Agency's capabilities, critical gaps, as well as potential actions the Agency could take to advance development and adoption of alternative methods. The FY 2024 President's Budget request builds on the FY 2023 Budget request to include an additional $1.5 million in funding within the Office of the Chief Scientist and further support the New Alternative Methods Program by providing strategic coordination, implementation, and oversight

and operational dollars to develop a qualification process to assess new alternative methods for regulatory use. The Agency looks forward to continued engagement with Congress and other stakeholders on this important issue.

FDA DRUG CONTROL PROGRAM AGENCY

Budget Authority (in millions)	FY 2022 Final	FY 2023 Enacted	FY 2024 Request
Drug Resources by Function			
Research and Development: Treatment & Prevention (CDER)	$20.50	$23.50	$43.05
Harm Reduction (non-add)	*$10.00*	*$10.00*	*$10.00*
Research and Development: Treatment & Prevention (CDRH)	$0.50	$1.50	$2.65
Interdiction (ORA)	$51.50	$54.50	$56.80
Total Drug Resources by Function	$72.50	$79.50	$102.50
Drug Resources by Decision Unit			
Center for Drug Evaluation and Research	$20.50	$23.50	$43.05
Center for Devices and Radiological Health	$0.50	$1.50	$2.65
Office of Regulatory Affairs	$51.50	$54.50	$56.80
Total Drug Resources by Decision Unit	$72.50	$79.50	$102.50
Drug Resources Personnel Summary			
Total FTEs (direct only)	178	196	209
Drug Resources as a percent of Budget			
Total Agency Budget (in Billions)	$3.367	$3.593	$3.963
Drug Resources percentage	2.15%	2.21%	2.59%

Figure 85 - 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.

FDA also recognizes the risk of 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 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' new Overdose Prevention Strategy, FDA is focusing our efforts on opioids and other controlled substances in the following four areas:

- 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 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 2024 Budget provides $102.5 million, an increase of $23.0 million above FY 2023 Enacted, for drug control program activities at FDA.

Center for Drug Evaluation and Research (CDER): FY 2024 Request: $43.05 million, an increase of $19.55 million above FY 2023 Enacted
The FY 2024 Budget for drug-related activities includes $43.05 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, and safe tapering of benzodiazepines; the first two 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 left-over 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/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 how payor coverage and health care resources impact real-world use of substance use disorder treatment and overdose reversal agents
- Enhancing the Opioid Data Warehouse, a cloud-based large data warehouse and analytical capability that allows FDA to better assess opioid vulnerability points in the population, anticipate changes in the opioid crisis, and target regulatory changes required for opioids
- 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
- 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.

FDA-supported research initiatives that have enhanced our understanding of appropriate opioids use 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 U.S., further work is needed to address the overdose crisis, including the impact of other addictive substances as well as the impact of the COVID-19 pandemic.

Center for Devices and Radiological Health (CDRH): FY 2024 Request: $2.65 million, an increase of $1.15 million above FY 2023 Enacted

The FY 2024 Budget for opioid-related activities includes $2.65 million for CDRH to continue supporting the use of digital health medical devices to help address opioid use disorder (OUD).

In FY 2023, CDRH will use the funds 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.

In FY 2022, CDRH commissioned a patient preference information (PPI) study on opioid use disorder (OUD). The study's goal is to better understand how patients prioritize outcomes associated with OUD and its treatments, the benefit/risk tradeoffs they are willing to make for certain therapies, and their preferences for features of digital health technologies and other interventions for OUD. The study may also help identify patient-perceived challenges or barriers

to accessing or using treatments for OUD. FDA will publish and present the results so all can benefit. In early FY 2023, CDRH held 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 for people living with OUD to share their experiences and begin suggesting opportunities or features of digital health technologies to support their recovery. Currently, a contractor is conducting a literature review to inform more detailed focus group discussions with people living with OUD and the work will continue through FY 2023.

In addition, CDRH will encourage the development of new and innovative medical devices to broaden the number of options and increase the effectiveness of OUD treatment during FY 2023. Contributions will include:

- 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.

In FY 2024, CDRH will:

- 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 Opioid Use Disorder
- Continue research and engagement/partnership with academic medical centers and others for 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 2024 Request: $56.8 million, an increase of $2.3 million above FY 2023 Enacted

The FY 2024 Budget includes $56.8 million for the ORA to establish staff with scientists, satellite laboratories at selected points of entry, including the International Mail Facilities (IMFs). ORA will expand its use of analytical tools expediting mail parcel screenings, and expand the current IMF initiative to interdict shipments of opioids, unapproved foreign drugs, counterfeit pharmaceuticals, and health fraud related shipments.

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% of refused drug products. After the SUPPORT Act was signed into law, FDA raised the overall destruction rate to 48% 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% 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 ORAs 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.

Additional information on FDA's approach to health equity may be found within the Executive Summary on page 4.

FDA SPECIFIC ITEMS

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

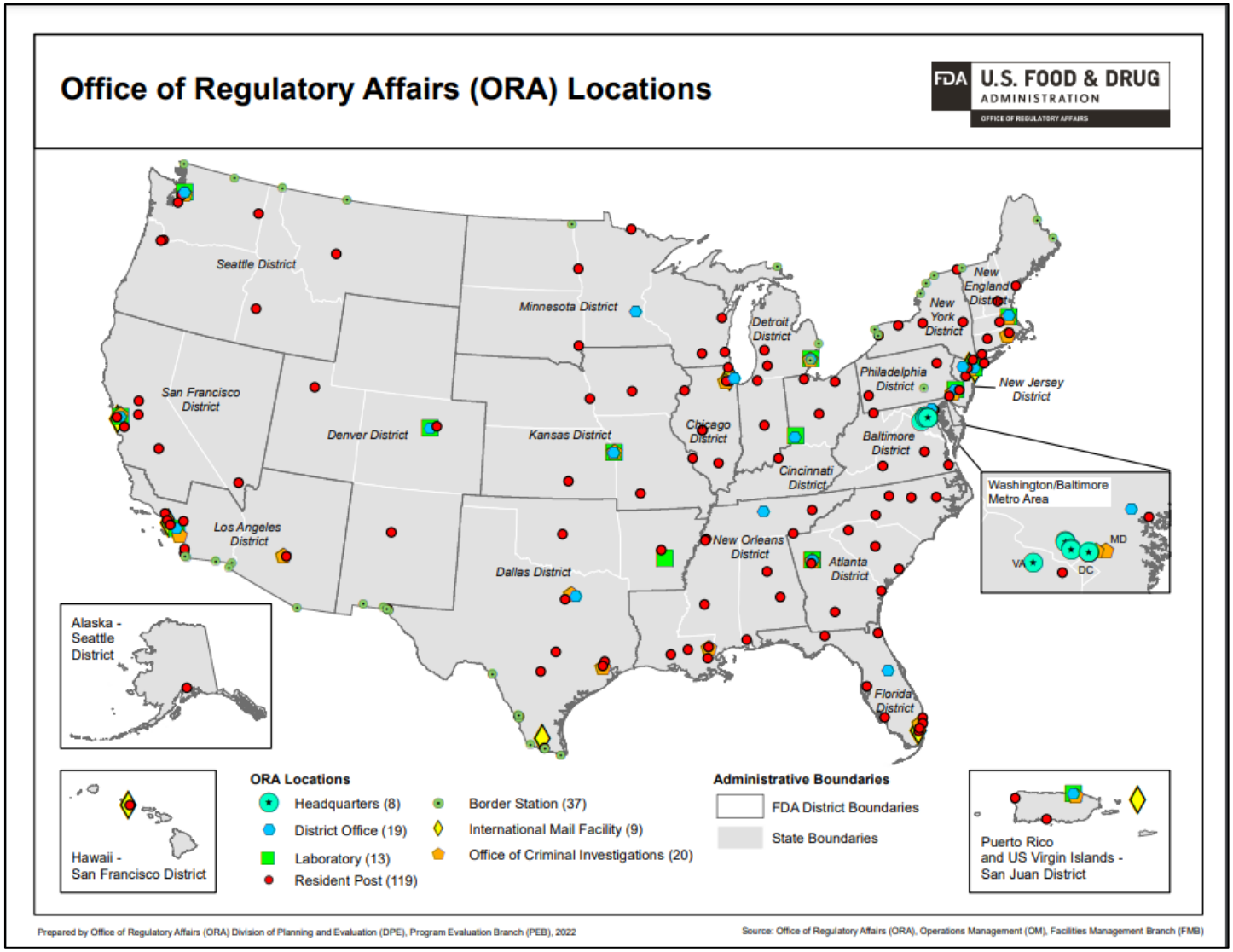

Figure 86 - Office of Regulatory Affairs (ORA) Locations

CROSSCUTS

Food and Drug Administration
FY 2022 - FY 2024 Crosscutting Information
(Program Level in Thousands)

(dollars in thousands)	**FY 2022 Estimate**	**FY 2023 Estimate**	**FY 2024 Estimate**
Alzheimer's Disease	13,457	13,892	14,478
HIV/AIDS	87,970	90,107	93,161
Antimicrobial Resistance	54,394	55,372	56,008
Bioterrorism-Medical Countermeasures	179,362	184,411	190,364
Cosmetics	8,775	9,221	14,216
Diabetes	29,270	30,296	31,413
Drug Abuse	15,827	16,319	17,064
Global Health	36,995	38,052	39,438
Immunization	174,770	179,604	184,998
Mental Health	13,781	14,040	14,703
Minority Health	10,443	12,933	12,736
Opioids 1/	72,500	79,500	102,500
Pandemic Influenza	26,197	26,855	27,653
Patient Safety	598,624	635,560	664,651
Pediatric Drugs	28,787	29,631	30,909
Tobacco 2/	712,000	712,000	812,000
Women's Health	67,274	68,295	69,948

*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 Levels for the Family Smoking Prevention and Tobacco Control Act

Figure 87 - Crosscuts

CENTRAL ACCOUNTS

Program (dollars in thousands)	FY 2022 Actuals		FY 2023 Estimates		FY 2024 Estimates	
	BA	UF	BA	UF	BA	UF
Foods	**20,571**	-	**22,255**	-	**22,255**	-
Center	4,946	-	5,975	-	5,975	-
Field	15,625	-	16,280	-	16,280	-
Human Drugs	**15,869**	**30,446**	**17,380**	**35,420**	**17,380**	**35,420**
Center	11,272	28,726	12,590	33,511	12,590	33,511
Field	4,597	1,720	4,790	1,909	4,790	1,909
Biologics	**5,390**	**4,424**	**6,041**	**5,725**	**6,041**	**5,725**
Center	4,061	4,361	4,656	5,649	4,656	5,649
Field	1,329	62	1,385	76	1,385	76
Animal Drugs and Feeds	**4,014**	**1,133**	**4,434**	**1,305**	**4,434**	**1,305**
Center	2,209	1,133	2,553	1,305	2,553	1,305
Field	1,805	-	1,881	-	1,881	-
Devices and Radiological Health	**9,942**	**5,154**	**10,709**	**7,584**	**10,709**	**7,584**
Center	7,092	4,972	7,740	7,377	7,740	7,377
Field	2,850	182	2,969	207	2,969	207
National Center for Toxicological Research	**948**	**-**	**1,338**	**-**	**1,338**	**-**
Family Smoking Prevention and Tobacco Control Act	-	**10,337**	-	**9,842**	**-**	**9,842**
Center	-	9,893	-	9,445	-	9,445
Field	-	444	-	397	-	397
FDA Headquarters	**7,657**	**3,642**	**6,788**	**4,736**	**6,788**	**4,736**
Total	**64,391**	**55,136**	**68,944**	**64,612**	**68,944**	**64,612**

Figure 88 - Central Accounts

HHS CHARGES AND ASSESSMENTS

Fiscal Year 2022 Actuals	
Assessments:	**317,864**
NIH eRA Grants Management System Pilot phase to support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System	315,217
Federal Audit Clearinghouse	2,647
Fee For Service:	**74,994,186**
Program Support Center/ Office of the Secretary Provides various services to the FDA, including some Information and Systems Management Services	**22,151,567**
Financial Management Portfolio (FMP)	558,387
Real Estate and Logistics Portfolio Includes facility building operations, shredding, storage, property disposal, forms and travel mgmt., board of corrections, printing, transhare, mail, property mgmt., shredding, storage, HHS Emergency mgmt., transportation policy, supply fulfillment	11,924,198
Equal Employment Opportunity Compliance and Operations Includes Complaint Investigations, FAD/Counseling, Mediation, National final agency decision	1,260,032
Assistance Secretary for Administration Labor and employee relations, Office of operations mgmt.	
Miscellaneous Services Includes AIM, Acquisition Reform, Category Mgmt., Commissioned Corps Force Mgmt (CCFM), Departmental Contracts Information System Program (DCIS), Ethics Program, Grants, Broadcast studio, HPO, Media Monitoring, OGC Claims, Small Business Consolidation, Strategic Planning, TAGGS, National Security Case Mgmt.	8,408,950
Occupational Health Portfolio FDA agency health units and services	**1,165,187**
Information & System Management Services	**38,974,795**
Unified Financial Management Systems (UFMS) Includes services for Consolidated Financial Reporting System (CFRS), Financial Business Intelligence System (FBIS), Governance and UFMS O&M support	14,301,457
HCAS Operations and Maintenance HCAS O&M services provide support for daily operations of the HCAS application.	2,864,000
Office of Operations	146,761
Office of Enterprise Services	1,827,827
Office of Chief Product 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, Data strategy and integration.	6,597,970
Office of Information Security (OIS) Includes computer security incident reponse center. Trusted Internet Connections and IT Security.	5,673,780
Digital Communications	7,563,000
Office of Human Resource Services Includes enterprise services, HR operations, payroll liaison, labor relations, systems planning and implemenation	**12,702,637**

Figure 89 - HHS Charges and Assessments Details 1 / 2

Jointly Funded Projects	**4,380,135**
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	1,565,500
CFO Audit of Financial Statements Audit services to be performed at the FDA in support of the fiscal year 2010 financial statement audit of the Department of Health and Human Services (DHHS) contracted and monitored by Office of the Inspector General (OIG) and its components, and related services.	566,083
Advisory Committee for Blood and Tissue Safety and Availability Agreement to provide funding for the advisory committee on Blood Safety	300,000
Regional Health Administrators 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
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
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
NIH Negotiation of Indirect Cost Rates Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations	37,549
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.	131,999
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
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.	86,038
Implementation of the Digital Accountability and Transparency Act (DATA)	65,027
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.	300,000
National Clinical Care Commission The Commission is required to establish a committee to evaluate and make recommendations regarding improvements to the coordination and leveraging of progams within the Department and other Federal agencies related to awareness and clinical care for at least one, but not more than two, complex metabolic or autoimmune diseases resulting from issues related to insulin that represent a significant disease burden in the US.	22,500
Secretary's Tribal Advisory Committee and Tribal Consultation 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
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.	50,232
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, Organzing, Vetting and Evaluating (IMPROVE) platform.	22,483
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
Federalwide Assurance Institutional Review Board Registration Database To modernize database tools used to fulfill statutory and regulatory responsibilities for the protection of human research subjects.	70,000
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 entir federal government by working in collaboration with the White House.	275,714

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DHHS Charges and Assessments Summary
FY 2022 Actual, and FY 2023 and 2024 Estimates

Activity	FY 2022 Estimate	FY 2023 Estimate	FY 2024 Estimate
Assessments	**$ 317,864**	**$ 356,981**	**$ 356,981**
Fee for Service	**$ 74,994,186**	**$ 88,350,411**	**$ 90,079,291**
Program Support Center/OS	$ 22,151,567	$ 23,579,488	$ 25,740,291
Occupational Health Portfolio	$ 1,165,187	$ 1,200,000	$ 1,200,000
Information System Management Service	$ 38,974,795	$ 46,048,310	$ 45,791,000
Office of Human Resource Services	$ 12,702,637	$ 17,522,613	$ 17,348,000
Jointly Funded Services	**$ 4,380,135**	**$ 4,683,772**	**$ 5,013,712**
Total	**$ 79,692,184**	**$ 93,391,164**	**$ 95,490,420**

Figure 91 – HHS Charges and Assessments Summary

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 FDA Super Office 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