DEPARTMENT of HEALTH and HUMAN SERVICES

Fiscal Year

2026

Food and Drug Administration

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LETTER FROM THE COMMISSIONER

I am pleased to present the U.S. Food and Drug Administration's (FDA) congressional justification for the fiscal year (FY) 2026 budget. The FY 2026 budget request of $6.8 billion is critical to supporting FDA's public health mission. FDA will use this funding to Make America Healthy Again through a major investment in the Human Foods Program (HFP), ensure Agency success through continuity of user fee funding so Americans can continue accessing novel medical products, and create greater efficiency through consolidation of work to core functions.

FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

As the oldest comprehensive consumer protection agency in the U.S. federal government, FDA is uniquely positioned to support the Make America Healthy Again (MAHA) initiative by ensuring the safety of our food and medical products. MAHA will transform public health by focusing on our nation's biggest public health challenge, the chronic disease epidemic plaguing the United States. Our children, our families, and our communities deserve pure, safe, and healthy food. In the first hundred days of the MAHA initiative, FDA has already taken major steps to remove petroleum-based dyes, overhaul the "Generally Recognized as Safe" (GRAS) designation, and launched Operation Stork Speed to ensure safe, reliable, and nutritious infant formula for American families. HFP funding is crucial to ensure the continued success and future wins of the MAHA initiative.

FDA will continue its gold-standard science to ensure the products it regulates are safe and effective. It will also focus on the root cause of illnesses and focus on cures rather than just managing disease. Americans deserve to understand their own bodies and take charge of their own healthcare decisions. FDA will focus on empowering patients through better diagnostics to equip Americans with the knowledge to make informed decisions for their individual health needs. This will help FDA rebuild public trust through promoting radical transparency. We must maintain the integrity of the scientific process by protecting expert recommendations from inappropriate influence and increasing transparency regarding existing data.

U.S. Food & Drug Administration
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The Agency takes its public health mandate seriously, and its focus is always on the well-being of patients and consumers. On behalf of FDA, I thank you for your support of FDA's vital work and its role in Making America Healthy Again.

Sincerely,

Martin A. Makary, M.D., M.P.H.
Commissioner of Food and Drugs

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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 human and animal health by ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of human and animal foods, cosmetics, and radiation-emitting products; and regulating tobacco products. FDA's customers and key stakeholders include American patients and consumers; healthcare professionals; regulated industry; academia; and, state, local, federal, and international governmental agencies.

OVERVIEW OF FY 2026 BUDGET REQUEST

(Dollars in Millions)	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 President's Budget +/- FY 2025 Enacted
Total Budget Authority Post Transfer	3,575.650	3,166.866	(408.784)
Total User Fees	3,451.133	3,588.394	137.261
Total Program Level	7,026.783	6,755.260	(271.523)

Figure 1 - Budget Overview

Americans depend on FDA to effectively manage its vast array of responsibilities to keep the nation's food and drugs safe. FDA's FY 2026 Budget proposes targeted investments to protect public health through the following priorities:

- Addressing the childhood chronic disease epidemic and Make America Healthy Again
- Ensuring Agency success through continuity of user fee funding
- Promoting efficiency through consolidation of work to core functions

FDA's proposed FY 2026 Budget reflects an overall decrease of 3.9 percent or $6.8 billion. This includes $3.2 billion in discretionary budget authority, a decrease of 11.4 percent or $408.8 million, and $3.6 billion in user fees, an increase of 4.0 percent or $137.3 million compared to the FY 2025 Enacted Budget.

FDA's FY 2026 Budget puts America first and strongly supports the Make America Healthy Again (MAHA) initiative. FDA will promote preventative healthcare and clean food initiatives to empower individuals and communities with access to healthier lifestyles. FDA will work to remove harmful compounds and toxic dyes out of the foods American children eat every day. FDA will enhance nutrition and food-related research to better inform regulatory decisions to promote the public health. The Agency will continue its gold-standard science and apply common sense to its regulatory decision making to improve public health.

The FDA ensures that Americans can access new products that improve their health in meaningful ways. FDA requires funding to ensure the safety and efficacy of medical products, particularly novel products that use innovative technology. FDA requires sufficient funding from

Congress to allow it to continue to collect fees from companies that produce certain products. These fees are called "user fees." These user fees help FDA ensure predictable timelines for product review and sustain staffing levels necessary to review products expeditiously. They also reduce the financial burden on the American taxpayer.

In alignment with the Administration's focus on promoting government efficiency, FDA has begun and will continue to consolidate work to core functions and mission-critical activities. FDA will restore public trust through radical transparency, effectiveness, and judicious financial management.

FY 2026 BUDGET – HIGHLIGHTS

(Dollars in Millions)	FY 2025	FY 2026	
	Enacted	President's Budget	FY 2026 President's Budget +/- FY 2025 Enacted
Budget Authority /1,2	**3,575.650**	**3,166.866**	**(408.784)**
Program Level	**7,026.783**	**6,755.260**	**(271.523)**
Enhancing Food Safety and Nutrition	**-**	**234.627**	**234.627**
HFP MAHA	-	234.627	234.627
Advancing Safe & Effective Medical Products	**50.000**	**118.209**	**68.209**
Devices Program	-	118.209	118.209
21st Century Cures	50.000	-	(50.000)
Consolidation to Core Functions	**-**	**(626.019)**	**(626.019)**
Contract Efficiencies	-	(169.431)	(169.431)
Reduction of the Bureaucracy	-	(456.588)	(456.588)
Infrastructure: Facilities Investments and Rent	**375.377**	**288.276**	**(87.101)**
White Oak	52.498	41.998	(10.500)
Other Rent and Rent Related	154.879	108.415	(46.464)
GSA Rental Payments	163.000	132.863	(30.137)
Buildings and Facilities	5.000	5.000	-
1/ The FY 2025 Enacted includes the post-reorganization level.			
2/ Inclusive of the $1.5 million net change for HHS Office of the Inspector General to support oversight of FDA's expanded authorities.			

Figure 2 - Executive Summary Table

The FY 2026 Budget includes $3.2 billion in budget authority, a decrease of 11.4 percent or $408.8 million below the FY 2025 Enacted Budget. Below outlines the movements within FDA's topline to meet the agency's mission in FY 2026.

- **Make America Healthy Again (+$234.6 million),** to address the nation's chronic disease epidemic, restore public trust in our food system, and strengthen our nation's nutritional and food safety. America is facing an unprecedented chronic disease crisis, with heart disease, diabetes, and obesity affecting millions of lives. Meanwhile, food safety failures, contamination events, and formula shortages have exposed systemic weaknesses in our food and nutrition infrastructure. This investment will ensure the safety of the U.S. food supply, invest in nutrition, prevent food safety failures, prevent infant formula contamination and shortages, and restore laboratory operations to conduct gold standard science. FDA requires funding to protect the nation's food supply by removing unsafe additives used in foods, help schools transition to healthier foods to ensure children are served wholesome food, and strengthen the food safety system to protect American consumers from preventable harm.

- **Continuity of User Fee Funding for Medical Devices (+$118.2 million)**, to sustain medical device review and research. Within this enhancement, $5.4 million is provided to advance MAHA initiatives as they pertain to improving health outcomes, supporting innovation, and reducing the burden of chronic diseases.
- **Promoting efficiency through Consolidation of Core Functions (-$626.0 million),** by streamlining functions across the Agency to save taxpayers money while preserving core services.
- **21st Century Cures (-$50 million),** due to end of the authorized funding from the 21st Century Cures Act
- **Infrastructure – Facilities Investments and Rent (-$87.1 million),** FDA continues to assess its infrastructure requirements to ensure alignment to the Administration's goals.
- **Office of the Inspector General (OIG) (+1.5 million),** inclusive of the net change for HHS OIG to support the oversight of FDA's expanded authorities. The budget eliminated this transfer and is not captured in FDA's totals.

Additional information on this request may be found within the various Program chapters on pages 18 (Human Foods Program), 25 (Human Drugs Program), 29 (Biologics Program), 35 (Animal Drugs and Foods Program), 40 (Devices Program), 46 (NCTR Program), 51 (Field), 58 (Field Lab Operations), 62 (Tobacco Program), 65 (Office of the Commissioner), 69 (Infrastructure), and 72 (Buildings and Facilities).

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BUDGET EXHIBITS

ALL PURPOSE TABLE

Food and Drug Administration
FY 2026 All Purpose Table
(Dollars in thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg		FY 2025 Enacted		FY 2026 President's Budget		President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Human Foods	**4,024**	**1,182,768**	**4,024**	**1,184,004**	**3,781**	**1,250,194**	**-243**	**66,190**
Budget Authority	***3,980***	***1,170,765***	***3,980***	***1,171,319***	***3,741***	***1,236,788***	***-239***	***65,469***
User Fees	***44***	***12,003***	***44***	***12,685***	***40***	***13,406***	***-4***	***721***
Center	1,987	581,847	1,987	577,197	1,835	649,853	-152	72,656
Budget Authority	1,984	580,769	1,984	576,058	1,832	648,650	-152	72,592
User Fees	3	1,078	3	1,139	3	1,203	—	64
Food and Feed Recall	1	268	1	283	1	299	—	16
Voluntary Qualified Importer Program	1	268	1	283	1	299	—	16
Third Party Auditor Program	1	542	1	573	1	605	—	32
Field	1,861	457,670	1,861	454,433	1,878	463,129	17	8,696
Budget Authority	1,820	446,745	1,820	442,887	1,841	450,926	21	8,039
User Fees	41	10,925	41	11,546	37	12,203	-4	657
Food and Feed Recall	4	1,104	4	1,167	3	1,233	-1	66
Food Reinspection	19	5,051	19	5,338	17	5,642	-2	304
Voluntary Qualified Importer Program	18	4,770	18	5,041	17	5,328	-1	287
Third Party Auditor Program	—	—	—	—	—	—	—	—
Field Laboratory Operations	176	143,251	176	152,374	68	137,212	-108	-15,162
Budget Authority	176	143,251	176	152,374	68	137,212	-108	-15,162
Human Drugs	**7,542**	**2,338,496**	**8,057**	**2,428,505**	**6,858**	**2,368,131**	**-1,199**	**-60,374**
Budget Authority	***2,245***	***719,679***	***2,245***	***724,168***	***1,908***	***593,618***	***-337***	***-130,550***
User Fees	***5,297***	***1,618,817***	***5,812***	***1,704,337***	***4,950***	***1,774,513***	***-862***	***70,176***
Center	6,409	2,069,312	6,873	2,152,251	5,801	2,143,968	-1,072	-8,283
Budget Authority	1,366	520,649	1,366	521,040	1,138	445,400	-228	-75,640
User Fees	5,043	1,548,663	5,507	1,631,211	4,663	1,698,568	-844	67,357
Prescription Drug (PDUFA)	3,200	1,022,037	3,381	1,052,115	2,845	1,095,067	-536	42,952
Generic Drug (GDUFA)	1,654	497,654	2,011	528,495	1,734	550,606	-277	22,111
Biosimilars (BsUFA)	187	28,235	113	49,822	82	52,072	-31	2,250
Outsourcing Facility	2	737	2	779	2	823	—	44
Field	997	235,427	1,048	238,320	1,004	207,256	-44	-31,064
Budget Authority	743	165,273	743	165,194	717	131,311	-26	-33,883
User Fees	254	70,154	305	73,126	287	75,945	-18	2,819
Prescription Drug (PDUFA)	40	8,513	37	8,646	33	8,959	-4	313
Generic Drug (GDUFA)	205	60,200	259	62,358	246	64,772	-13	2,414
Biosimilars (BsUFA)	8	1,087	7	1,748	6	1,819	-1	71
Outsourcing Facility	1	354	2	374	2	395	—	21
Field Laboratory Operations	136	33,757	136	37,934	53	16,907	-83	-21,027
Budget Authority	136	33,757	136	37,934	53	16,907	-83	-21,027

Figure 3 - All-Purpose Table (1/6)

Food and Drug Administration

FY 2026 All Purpose Table

(Dollars in thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg		FY 2025 Enacted		FY 2026 President's Budget		President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Biologics	**1,641**	**571,811**	**1,730**	**607,060**	**1,470**	**562,544**	**-260**	**-44,516**
Budget Authority	***827***	***268,068***	***827***	***268,197***	***715***	***204,985***	***-112***	***-63,212***
User Fees	***814***	***303,743***	***903***	***338,863***	***755***	***357,559***	***-148***	***18,696***
Center	1,422	525,350	1,505	560,268	1,246	522,798	-259	-37,470
Budget Authority	614	224,047	614	224,144	503	168,110	-111	-56,034
User Fees	808	301,303	891	336,124	743	354,688	-148	18,564
Prescription Drug (PDUFA)	740	281,434	817	312,561	682	330,169	-135	17,608
Medical Device (MDUFA)	61	18,503	67	21,718	56	22,597	-11	879
Generic Drug (GDUFA)	4	1,069	4	1,131	3	1,181	-1	50
Biosimilars (BsUFA)	3	297	3	714	2	741	-1	27
Field	218	46,216	224	46,547	223	39,654	-1	-6,893
Budget Authority	212	43,776	212	43,808	211	36,783	-1	-7,025
User Fees	6	2,440	12	2,739	12	2,871	—	132
Prescription Drug (PDUFA)	6	2,440	11	2,569	11	2,701	—	132
Medical Device (MDUFA)	---	---	1	170	1	170	—	---
Field Laboratory Operations	1	245	1	245	1	92	—	-153
Budget Authority	1	245	1	245	1	92	---	-153
Animal Drugs and Foods	**1,040**	**284,483**	**1,044**	**281,727**	**851**	**233,765**	**-193**	**-47,962**
Budget Authority	***829***	***228,574***	***829***	***228,708***	***681***	***174,919***	***-148***	***-53,789***
User Fees	***211***	***55,909***	***215***	***53,019***	***170***	***58,846***	***-45***	***5,827***
Center	779	226,648	783	224,051	614	185,752	-169	-38,299
Budget Authority	573	171,993	573	172,309	449	128,302	-124	-44,007
User Fees	206	54,655	210	51,742	165	57,450	-45	5,708
Animal Drug (ADUFA)	115	30,879	121	26,240	96	31,430	-25	5,190
Animal Generic Drug (AGDUFA)	91	23,653	89	25,372	69	25,883	-20	511
Third Party Auditor Program	---	123	---	130	---	137	—	7
Field	248	46,438	248	46,113	232	38,506	-16	-7,607
Budget Authority	243	45,184	243	44,836	227	37,110	-16	-7,726
User Fees	5	1,254	5	1,277	5	1,396	—	119
Animal Drug (ADUFA)	1	257	2	335	2	401	—	66
Animal Generic Drug (AGDUFA)	1	106	---	---	---	---	---	---
Food Reinspection	3	891	3	942	3	995	---	53
Third Party Auditor Program	---	---	---	---	---	---	---	—
Field Laboratory Operations	13	11,397	13	11,563	5	9,507	-8	-2,056
Budget Authority	13	11,397	13	11,563	5	9,507	-8	-2,056

Figure 4 - All-Purpose Table (2/6)

Food and Drug Administration

FY 2026 All Purpose Table

(Dollars in thousands)

(Dollars in Thousands)	FY 2024		FY 2025		FY 2026			
	Final Post-Reorg		Enacted		President's Budget		President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Devices and Radiological Health	**2,540**	**791,300**	**2,680**	**841,316**	**2,219**	**883,014**	**-461**	**41,698**
Budget Authority	***1,520***	***445,593***	***1,520***	***446,660***	***1,260***	***454,874***	***-260***	***8,214***
User Fees	***1,020***	***345,707***	***1,160***	***394,656***	***959***	***428,140***	***-201***	***33,484***
Center	2,068	701,761	2,206	750,408	1,792	790,381	-414	39,973
Budget Authority	1,066	359,500	1,066	359,749	853	366,365	-213	6,616
User Fees	1,002	342,261	1,140	390,659	939	424,016	-201	33,357
Prescription Drug (PDUFA)	15	2,138	17	5,567	14	5,789	-3	222
Medical Device (MDUFA)	959	321,590	1094	366,559	902	399,694	-192	33,135
Mammography Quality Standards Act (MQSA)	28	18,533	29	18,533	23	18,533	-6	---
Field	440	81,357	442	81,977	414	83,538	-28	1,561
Budget Authority	422	77,911	422	77,980	394	79,414	-28	1,434
User Fees	18	3,446	20	3,997	20	4,124	---	127
Medical Device (MDUFA)	10	2,323	11	2,874	11	3,001	---	127
Mammography Quality Standards Act (MQSA)	8	1,123	9	1,123	9	1,123	---	---
Field Laboratory Operations	32	8,182	32	8,931	13	9,095	-19	164
Budget Authority	32	8,182	32	8,931	13	9,095	-19	164
National Center for Toxicological Research (BA Only)	**287**	**77,790**	**287**	**77,740**	**209**	**56,307**	**-78**	**-21,433**
Tobacco	**1,311**	**684,760**	**1,358**	**688,827**	**1,047**	**689,258**	**-311**	**431**
Center	**1,213**	**662,061**	**1,263**	**662,487**	**957**	**661,282**	**-306**	**-1,205**
User Fees	1,213	662,061	1,263	662,487	957	661,282	-306	-1,205
Family Smoking Prevention and Tobacco Control Act	1,213	662,061	1,263	662,487	957	661,282	-306	-1,205
Field	**61**	**14,867**	**52**	**13,448**	**47**	**14,282**	**-5**	**834**
Family Smoking Prevention and Tobacco Control Act	61	14,867	52	13,448	47	14,282	-5	834
Field Laboratory Operations	**37**	**7,832**	**43**	**12,892**	**43**	**13,694**	**—**	**802**
Family Smoking Prevention and Tobacco Control Act	37	7,832	43	12,892	43	13,694	---	802
Office of the Commissioner	**1,005**	**382,849**	**1,056**	**364,043**	**270**	**291,318**	**-786**	**-72,725**
Budget Authority	613	241,304	613	234,981	142	157,099	-471	-77,882
User Fees	***392***	***141,545***	***443***	***129,062***	***128***	***134,219***	***-315***	***5,157***
Prescription Drug (PDUFA)	220	72,512	242	65,627	73	67,929	-169	2,302
Medical Device (MDUFA)	34	11,848	37	11,953	11	12,431	-26	478
Generic Drug (GDUFA)	79	42,835	89	36,642	28	37,990	-61	1,348
Biosimilars (BsUFA)	8	1,343	9	793	3	822	-6	29
Animal Drug (ADUFA)	4	1,024	5	722	2	864	-3	142
Animal Generic Drug (AGDUFA)	3	741	4	32	2	33	-2	1
Family Smoking Prevention and Tobacco Control Act	40	9,693	53	11,662	9	12,431	-44	769
Mammography Quality Standards Act (MQSA)	---	102	---	102	---	102	---	---
Food and Feed Recall	---	83	---	88	---	93	---	5
Food Reinspection	2	529	2	559	---	591	-2	32
Voluntary Qualified Importer Program	1	306	1	323	---	342	-1	19
Third Party Auditor Program	---	43	---	45	---	48	---	3
Outsourcing Facility	1	486	1	514	---	543	-1	29

Figure 5 - All-Purpose Table (3/6)

Food and Drug Administration
FY 2026 All Purpose Table
(Dollars in thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg		FY 2025 Enacted		FY 2026 President's Budget		FY 2026 President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
FDA White Oak Campus	—	**55,061**	—	**54,917**	—	**44,612**	—	**-10,305**
Budget Authority	—	52,498	—	52,498	—	41,998	—	-10,500
User Fees	---	***2,563***	---	***2,419***	---	***2,614***	---	***195***
Prescription Drug (PDUFA)	—	—	—	—	—	—	—	—
Medical Device (MDUFA)	—	—	—	—	—	—	—	—
Generic Drug (GDUFA)	—	—	—	—	—	—	—	—
Biosimilars (BsUFA)	—	—	—	—	—	—	—	—
Animal Drug (ADUFA)	—	—	—	—	—	—	—	—
Animal Generic Drug (AGDUFA)	—	—	—	—	—	—	—	—
Family Smoking Prevention and Tobacco Control Act	—	2,563	—	2,419	—	2,614	—	195
Other Rent and Rent Related	—	**161,165**	—	**160,259**	—	**113,826**	—	**-46,433**
Budget Authority	—	154,879	—	154,879	—	108,415	—	-46,464
User Fees	---	***6,286***	---	***5,380***	---	***5,411***	---	***31***
Prescription Drug (PDUFA)	—	—	—	—	—	—	—	—
Medical Device (MDUFA)	—	—	—	—	—	—	—	—
Generic Drug (GDUFA)	—	—	—	—	—	—	—	—
Biosimilars (BsUFA)	—	—	—	—	—	—	—	—
Animal Drug (ADUFA)	—	335	—	559	—	662	—	103
Animal Generic Drug (AGDUFA)	—	250	—	237	—	235	—	-2
Family Smoking Prevention and Tobacco Control Act	—	5,176	—	4,028	—	3,928	—	-100
Food and Feed Recall	—	48	—	51	—	54	—	3
Food Reinspection	—	224	—	237	—	250	—	13
Voluntary Qualified Importer Program	—	188	—	199	—	210	—	11
Third Party Auditor Program	—	27	—	29	—	30	—	1
Outsourcing Facility	—	38	—	40	—	42	—	2
GSA Rental Payments	—	**228,038**	—	**220,288**	—	**190,507**	—	**-29,781**
Budget Authority	—	163,000	—	163,000	—	132,863	—	-30,137
User Fees	---	***65,038***	---	***57,288***	---	***57,644***	---	***356***
Prescription Drug (PDUFA)	—	33,030	—	31,884	—	32,652	—	768
Medical Device (MDUFA)	—	8,117	—	7,718	—	7,915	—	197
Generic Drug (GDUFA)	—	11,780	—	10,404	—	10,889	—	485
Biosimilars (BsUFA)	—	147	—	270	—	277	—	7
Animal Drug (ADUFA)	—	1,005	—	652	—	785	—	133
Animal Generic Drug (AGDUFA)	—	250	—	343	—	352	—	9
Family Smoking Prevention and Tobacco Control Act	—	9,808	—	5,064	—	3,769	—	-1,295
Food and Feed Recall	—	81	—	86	—	90	—	4
Food Reinspection	—	384	—	406	—	429	—	23
Voluntary Qualified Importer Program	—	320	—	338	—	357	—	19
Third Party Auditor Program	—	52	—	55	—	58	—	3
Outsourcing Facility	—	64	—	68	—	71	—	3
Color Certification	37	11,109	37	11,109	37	11,109	—	—
Export Certification	26	5,185	26	5,185	26	5,185	—	—
Priority Review Vouchers (PRV) Tropical Disease	—	2,713	—	2,867	—	3,030	—	163
Priority Review Vouchers (PRV) Pediatric Disease	11	8,486	11	8,969	11	9,479	—	510
Priority Review Vouchers (PRV) Medical Countermeasures	—	2,713	—	—	—	—	—	—
Over the Counter Monograph	93	31,800	96	36,467	96	37,981	—	1,514
Food and Drug Safety -- No Year (P.L. 113-6)	—	—	—	—	—	—	—	—
21st Century Cures (BA Only)	187	50,000	187	50,000	—	—	-187	-50,000
Foreign Inspection Pilot - No Year	—	—	—	—	—	—	—	—
Opioids - No Year	—	—	—	—	—	—	—	—
Subtotal, Salaries and Expenses	**19,744**	**6,870,527**	**20,593**	**7,023,283**	**16,875**	**6,750,260**	**-3,718**	**-273,023**
Buildings and Facilities (Budget Authority)	—	**5,000**	—	**5,000**	—	**5,000**	—	—

Figure 6 – All Purpose Table (4/6)

Food and Drug Administration
FY 2026 All Purpose Table
(Dollars in thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg		FY 2025 Enacted		FY 2026 President's Budget		President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
FDA White Oak Campus	—	**55,061**	—	**54,917**	—	**44,612**	—	**-10,305**
Budget Authority	---	52,498	---	52,498	---	41,998	—	-10,500
User Fees	---	***2,563***	---	***2,419***	---	***2,614***	---	***195***
Total Program Level	**19,744**	**6,875,527**	**20,593**	**7,028,283**	**16,875**	**6,755,260**	**-3,718**	**-273,023**
Non-Field Activities	*15,337*	*5,289,624*	*16,130*	*5,433,042*	*12,894*	*5,368,443*	*-3,236*	*-64,599*
Field Activities	*3,825*	*881,975*	*3,875*	*880,838*	*3,798*	*846,365*	*-77*	*-34,473*
Field Lab Activities	*395*	*204,664*	*401*	*223,939*	*183*	*186,507*	*-218*	*-37,432*
White Oak, Rent Activities, and B&F	---	*449,264*	---	*440,464*	---	*353,945*	---	*-86,519*
Food and Drug Safety -- No Year	---	---	---	---	---	---	---	---
Foreign Inspection Pilot - No Year	---	---	---	---	---	---	---	---
Opioids - No Year	---	---	---	---	---	---	---	---
21st Century Cures	*187*	*50,000*	*187*	*50,000*	---	---	*-187*	*-50,000*
User Fees:								
Current Law								
Prescription Drug (PDUFA)	*4,221*	*1,422,104*	*4,505*	*1,478,969*	*3,658*	*1,543,266*	*-847*	*64,297*
Medical Device (MDUFA)	*1,064*	*362,381*	*1,210*	*410,992*	*981*	*445,808*	*-229*	*34,816*
Generic Drug (GDUFA)	*1,942*	*613,538*	*2,363*	*639,030*	*2,011*	*665,438*	*-352*	*26,408*
Biosimilars (BsUFA)	*206*	*31,109*	*132*	*53,347*	*93*	*55,731*	*-39*	*2,384*
Animal Drug (ADUFA)	*120*	*33,500*	*128*	*28,508*	*100*	*34,142*	*-28*	*5,634*
Animal Generic Drug (AGDUFA)	*95*	*25,000*	*93*	*25,984*	*71*	*26,503*	*-22*	*519*
Family Smoking Prevention and Tobacco Control Act	*1,351*	*712,000*	*1,411*	*712,000*	*1,056*	*712,000*	*-355*	---
Subtotal, Current Law	**8,999**	**3,199,632**	**9,842**	**3,348,830**	**7,970**	**3,482,888**	**-1,872**	**134,058**
Indefinite								
Mammography Quality Standards Act (MQSA)	*36*	*19,758*	*38*	*19,758*	*32*	*19,758*	*-6*	---
Color Certification	*37*	*11,109*	*37*	*11,109*	*37*	*11,109*	---	---
Export Certification	*26*	*5,185*	*26*	*5,185*	*26*	*5,185*	---	---
Priority Review Vouchers (PRV) Tropical Disease	---	*2,713*	---	*2,867*	---	*3,030*	---	*163*
Priority Review Vouchers (PRV) Pediatric Disease	*11*	*8,486*	*11*	*8,969*	*11*	*9,479*	---	*510*
Priority Review Vouchers (PRV) Medical Countermeasures	---	*2,713*	---	---	---	---	---	---
Food and Feed Recall	*5*	*1,584*	*5*	*1,675*	*4*	*1,769*	*-1*	*94*
Food Reinspection	*24*	*7,079*	*24*	*7,482*	*20*	*7,907*	*-4*	*425*
Voluntary Qualified Importer Program	*20*	*5,852*	*20*	*6,184*	*18*	*6,536*	*-2*	*352*
Third Party Auditor Program	*1*	*787*	*1*	*832*	*1*	*878*	---	*46*
Outsourcing Facility	*4*	*1,679*	*5*	*1,775*	*4*	*1,874*	*-1*	*99*
Over the Counter Monograph	*93*	*31,800*	*96*	*36,467*	*96*	*37,981*	---	*1,514*
Subtotal, Indefinite	**257**	**98,745**	**263**	**102,303**	**249**	**105,506**	**-14**	**3,203**

Figure 7 - All-Purpose Table (5/6)

Food and Drug Administration

FY 2026 All Purpose Table

(Dollars in thousands)

(Dollars in Thousands)	FY 2024		FY 2025		FY 2026			
	Final Post-Reorg		Enacted		President's Budget		President's Budget +/- FY 2025 Enacted	
	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Total User Fees	**9,256**	**3,298,377**	**10,105**	**3,451,133**	**8,219**	**3,588,394**	**-1,886**	**137,261**
Total Budget Authority, Pre-Transfer	**10,488**	**3,577,150**	**10,488**	**3,577,150**	**8,656**	**3,166,866**	**-1,832**	**-410,284**
BA, S&E	*10,301*	*3,522,150*	*10,301*	*3,522,150*	*8,656*	*3,161,866*	*-1,645*	*-360,284*
BA, B&F	---	*5,000*	---	*5,000*	---	*5,000*	---	---
Food and Drug Safety (No-Year)	---	---	---	---	---	---	---	---
21st Century Cures	*187*	*50,000*	*187*	*50,000*	---	---	*-187*	*-50,000*
Foreign Inspection Pilot - No Year	---	---	---	---	---	---	---	---
Opioids - No Year	---	---	---	---	---	---	---	---
Total Program Level, Pre-Transfer	**19,744**	**6,875,527**	**20,593**	**7,028,283**	**16,875**	**6,755,260**	**-3,718**	**-273,023**
HHS OIG transfer (BA Only)	**—**	**-1,500**	**—**	**-1,500**	**—**	**—**	**—**	**1,500**
Total Budget Authority, Post-Transfer	**10,488**	**3,575,650**	**10,488**	**3,575,650**	**8,656**	**3,166,866**	**-1,832**	**-408,784**
Total User Fees	**9,256**	**3,298,377**	**10,105**	**3,451,133**	**8,219**	**3,588,394**	**-1,886**	**137,261**
Total Program Level, Post-Transfer	**19,744**	**6,874,027**	**20,593**	**7,026,783**	**16,875**	**6,755,260**	**-3,718**	**-271,523**
NEF	**—**	**62,600**	**—**	**—**	**—**	**—**	**—**	**—**

*FY 2024 Actuals do not include $31.96M COVID-19 Supplemental, $385,000 Hurricane Supplemental, and $48.781M collections & refunds.

** FY 2024 Actual FTE figures do not include 40 reimbursable, 3 FOIA, 12 PEPFAR, 30 HCFAC, and 31 COVID-19 Supplemental.

***FY 2024 Final level includes Sec 905 BA/UF swap, ORA/OGPS transfer, and an updated FY 2024 comparability adjustment. User fee estimates are consistent with the Joint Explanatory Statement.

****FY 2024 Final level reflects Transfer/Reprogramming notification reducing GSA Rent by $3.286M and Center, Field, and HQ by $4.714M to address the $8M reduction in the FY 2024 Enacted Bill. Additionally, this level reflects a transfer of $2.089M from Foods Center to HQ to support work on CBD and other cannabis-derived products. This level also includes a realignment of $3.5M from Foods Center to HQ to implement MoCRA.

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

******FY 2025 Enacted is reflective of the FY 2025 Full Year CR level.

*******FY 2026 user fee estimates reflect the 5yr plan estimated target revenue.

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

*********FY 2026 FTE levels reflect estimates for October 1, 2025 and may not represent expected FTE levels across FY 2026. These estimates are subject to

**********Over-the-Counter Monograph Drug User Fee Act (OMUFA) is set to expire September 30, 2025. Proposed reauthorizing legislation would enable FDA to continue to collect user fees in FY 2026 and beyond. The FY 2026 fee revenue assumes timely reauthorization and is based on current estimates.

***********The Priority Review Voucher for Pediatric Rare Diseases sunset December 2024. Proposed legislation is under consideration that would authorize FDA to continue collecting fees for Pediatric PRVs. The FY 2026 PB reflects current estimates.

Figure 8 – All Purpose Table (6/6)

BUDGET AUTHORITY CROSSWALK

FY 2026 JUSTIFICATION CROSSWALK

Food and Drug Administration
FY 2026 Congressional Justification Crosswalk

(Dollars in Thousands)	FY 2025 Enacted		FY 2026 CJ																FY 2026 President's Budget	
			Consolidation to Core Functions				Infrastructure and B&F		Enhancing Food Safety and Nutrition				Advancing Medical Product Safety				Total Changes			
			Contract Efficiencies		Reduction of the Federal Bureaucracy				HFP MAHA		Total Food Safety		Devices Program		Total Medical Product Safety					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																				
Human Foods	**3,980**	**1,171,319**	—	**-12,801**	**-534**	**-156,357**	—	—	**295**	**234,627**	**295**	**234,627**	—	—	—	—	**-239**	**65,469**	**3,741**	**1,236,788**
Center	1,984	576,058	—	3,763	-308	-86,955	—	—	156	155,784	156	155,784	—	--	--	--	-152	72,592	1,832	648,650
Field	1,820	442,887	—	-21,473	-118	-42,488	—	—	139	72,000	139	72,000	—	--	--	--	21	8,039	1,841	450,926
Field Laboratory Operations	176	152,374	—	4,909	-108	-26,914	—	—	--	6,843	—	6,843	—	--	--	--	-108	-15,162	68	137,212
Human Drugs	**2,245**	**724,168**	—	**-41,709**	**-337**	**-88,841**	—	—	—	—	—	—	—	—	—	—	**-337**	**-130,550**	**1,908**	**593,618**
Center	1,366	521,040	—	-20,813	-228	-54,827	—	—	--	--	--	--	--	--	--	--	-228	-75,640	1,138	445,400
Field	743	165,194	—	-20,666	-26	-13,217	—	—	--	--	--	--	--	--	--	--	-26	-33,883	717	131,311
Field Laboratory Operations	136	37,934	—	-230	-83	-20,797	—	—	--	--	--	--	--	--	--	--	-83	-21,027	53	16,907
Biologics	**827**	**268,197**	—	**-29,564**	**-112**	**-33,648**	—	—	—	—	—	—	—	—	—	—	**-112**	**-63,212**	**715**	**204,985**
Center	614	224,144	—	-27,546	-111	-28,488	—	—	--	--	--	--	--	--	--	--	-111	-56,034	503	168,110
Field	212	43,808	—	-2,017	-1	-5,008	—	—	--	--	--	--	--	--	--	--	-1	-7,025	211	36,783
Field Laboratory Operations	1	245	—	-1	--	-152	—	—	--	--	--	--	--	--	--	--	--	-153	1	92
Animal Drugs and Foods	**829**	**228,708**	—	**-8,359**	**-148**	**-45,430**	—	—	—	—	—	—	—	—	—	—	**-148**	**-53,789**	**681**	**174,919**
Center	573	172,309	—	-6,226	-124	-37,781	—	—	--	--	--	--	--	--	--	--	-124	-44,007	449	128,302
Field	243	44,836	—	-2,064	-16	-5,662	—	—	--	--	--	--	--	--	--	--	-16	-7,726	227	37,110
Field Laboratory Operations	13	11,563	—	-69	-8	-1,987	—	—	--	--	--	--	--	--	--	--	-8	-2,056	5	9,507
Devices and Radiological Health	**1,520**	**446,660**	—	**-25,804**	**-260**	**-84,191**	—	—	—	—	—	—	—	**118,209**	—	**118,209**	**-260**	**8,214**	**1,260**	**454,874**
Center	1,066	359,749	—	-22,160	-213	-73,385	—	—	--	--	--	--	--	102,161	—	102,161	-213	6,616	853	366,365
Field	422	77,980	—	-3,590	-28	-10,045	—	—	--	--	--	--	--	15,069	—	15,069	-28	1,434	394	79,414
Field Laboratory Operations	32	8,931	—	-54	-19	-761	—	—	--	--	--	--	--	979	—	979	-19	164	13	9,095

Figure 9 - Budget Authority Crosswalk (1/2)

Food and Drug Administration
FY 2026 Congressional Justification Crosswalk

(Dollars in Thousands)	FY 2025 Enacted		FY 2026 CJ																FY 2026 President's Budget	
			Consolidation to Core Functions				Infrastructure and B&F		Enhancing Food Safety and Nutrition				Advancing Medical Product Safety				Total Changes			
			Contract Efficiencies		Reduction of the Federal Bureaucracy				HFP MAHA		Total Food Safety		Devices Program		Total Medical Product Safety					
	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000	FTE	$000
Salaries and Expenses Account:																				
National Center for Toxicological Research	287	77,740	—	-7,966	-78	-13,467	—	—	—	—	—	—	—	—	—	—	-78	-21,433	209	56,307
Office of the Commissioner	613	234,981	—	-43,228	-471	-34,654	—	—	—	—	—	—	—	—	—	—	-471	-77,882	142	157,099
FDA White Oak Campus	—	52,498	—	—	—	—	—	-10,500	—	—	—	—	—	—	—	—	—	-10,500	—	41,998
Other Rent and Rent Related	—	154,879	—	—	—	—	—	-46,464	—	—	—	—	—	—	—	—	—	-46,464	—	108,415
GSA Rental Payments	—	163,000	—	—	—	—	—	-30,137	—	—	—	—	—	—	—	—	—	-30,137	—	132,863
Subtotal, Salaries and Expenses Account	10,301	3,522,150	—	-169,431	-1,940	-456,588	—	-87,101	295	234,627	295	234,627	—	118,209	—	118,209	-1,645	-360,284	8,656	3,161,866
Buildings and Facilities Account	—	5,000	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	5,000
Total Budget Authority, Pre-Transfer	10,301	3,527,150	—	-169,431	-1,940	-456,588	—	-87,101	295	234,627	295	234,627	—	118,209	—	118,209	295	265,735	8,656	3,166,866
Non-Field Activities	6,503	2,166,021	—	-124,176	-1,533	-329,557	—	—	156	155,784	156	155,784	—	102,161	—	102,161	-1,377	-195,788	5,126	1,970,233
Field Activities	3,440	774,705	—	-49,810	-189	-76,420	—	—	139	72,000	139	72,000	—	15,069	—	15,069	-50	-39,161	3,390	735,544
Field Lab Activities	358	211,047	—	4,555	-218	-50,611	—	—	—	6,843	—	6,843	—	979	—	979	-218	-38,234	140	172,813
Rent Activities, B&F, and White Oak	—	375,377	—	—	—	—	—	-87,101	—	—	—	—	—	—	—	—	—	-87,101	—	288,276
21st Century Cures	187	50,000	—	—	—	—	—	—	—	—	—	—	—	—	-187	-50,000	-187	-50,000	—	—
Total Budget Authority with 21st Century Cures	10,488	3,577,150	—	-169,431	-1,940	-456,588	—	-87,101	295	234,627	295	234,627	—	118,209	-187	68,209	-1,832	-410,284	8,656	3,166,866
HHS OIG transfer	—	-1,500	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	1,500	—	—
Total Budget Authority, Post-Transfer	10,488	3,575,650	—	-169,431	-1,940	-456,588	—	-87,101	295	234,627	295	234,627	—	118,209	-187	68,209	-1,832	-408,784	8,656	3,166,866

FY 2026 FTE levels reflect estimates for October 1, 2025 and may not represent expected FTE levels across FY 2026. These estimates are subject to change.

Figure 10 – Budget Authority Crosswalk (2/2)

SUMMARY OF CHANGES

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

FY 2025 Estimate	
Total estimated budget authority	$3,575.650
(Obligations)	
FY 2026 President's Budget	
Total estimated budget authority	$3,166.866
(Obligations)	
Net Change	-$408.784

	FY 2025 Estimate		FY 2026 President's Budget		FY 2026 +/- FY 2025	
	FTE	BA	FTE	BA	FTE	BA
Increases:						
Food Safety						
Human Foods Program MAHA	--	--	--	$234.627	--	+$234.627
Medical Product Safety						
Devices Program	--	--	--	$118.209	--	+$118.209
Subtotal, Program Increases	--	--	--	**$352.836**	--	**+$352.836**
Total Increases	--	--	--	**$352.836**	--	**+$352.836**
Decreases:						
Infrastructure (WO & OR&RR) and GSA Rent.	--	$370.377	--	$283.276	--	-$87.101
Consolidation to Core Functions						
Contract Efficiencies	--	--	--	-$169.431	--	-$169.431
Reduction of the Federal Bureaucracy	--	--	--	-$456.588	--	-$456.588
Medical Product Safety						
21st Century Cures	--	$50.000	--	--	--	-$50.000
Subtotal, Program Decreases	--	**$420.377**	--	**-$342.743**	--	**-$763.120**
Total Decreases	--	**$420.377**	--	**-$342.743**	--	**-$763.120**
Net Change/2	--	**$420.377**	--	**$10.093**	--	**-$410.284**

1/ The FY 2026 President's Budget also includes $137.3 million in user fee increases.
2/ Excludes the $1.5 million net change for HHS Office of the Inspector General to support oversight of FDA's expanded authorities.

Figure 11 – Summary of Changes

APPROPRIATIONS HISTORY

Salaries and Expenses

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation:				
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				
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	6,610,830,000	6,656,830,000	6,753,582,000
FY 2025	6,964,541,000	6,782,433,000	6,908,872,000	6,907,447,000
FY 2026	6,682,750,000			

* Excludes Indefinite user fees.

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

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

**** 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 12 – Salaries & Expenses Appropriations History

Buildings and Facilities

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation:				
FY 2016	8,788,000	8,788,000	8,788,000	8,788,000
FY 2017	11,788,000	11,788,000	11,788,000	11,788,000
FY 2018	8,771,000	8,771,000	11,788,000	11,788,000
FY 2019	11,788,000	11,788,000	11,788,000	11,788,000
FY 2020	11,788,000	11,788,000	11,788,000	11,788,000
FY 2021	13,788,000	11,788,000	13,788,000	12,788,000
FY 2022	30,788,000	21,788,000	15,288,000	12,788,000
FY 2023	30,788,000	16,000,000	30,788,000	12,788,000
FY 2024	18,788,000	---	12,788,000	5,000,000
FY 2025	12,788,000	---	9,000,000	5,000,000
FY 2026	5,000,000			

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

Figure 13 – Buildings & Facilities Appropriations History

NARRATIVE BY ACTIVITY

HUMAN FOODS

PROGRAM DESCRIPTION

The Human Foods Program (HFP) oversees all FDA activities related to food safety and nutrition. HFP's mission is to ensure that food is a source of wellness and to protect and promote the health and wellbeing of all people through science-based approaches to preventing foodborne illness, reducing diet-related chronic disease, and ensuring chemicals in food are safe. Currently, the United States is facing an unprecedented increase in chronic diseases. This harms the American public, our economy, and our security. As nutrition is the foundation of health, FDA is uniquely positioned to support MAHA and fight back against this epidemic. FDA is working to safeguard the health of our children and ensure they are nourished in a way that promotes health and longevity over the course of their lives.

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Human Foods	**1,131,315**	**1,195,893**	**1,182,768**	**1,184,004**	**1,250,194**	**66,190**
Budget Authority	***1,131,315***	***1,195,863***	***1,170,765***	***1,171,319***	***1,236,788***	***65,469***
User Fees	**---**	***30***	***12,003***	***12,685***	***13,406***	***721***
Center	367,150	401,812	581,847	577,197	649,853	72,656
Budget Authority	367,150	401,812	580,769	576,058	648,650	72,592
User Fees	---	---	1,078	1,139	1,203	64
Field	764,165	794,081	457,670	454,433	463,129	8,696
Budget Authority	764,165	794,051	446,745	442,887	450,926	8,039
User Fees	---	30	10,925	11,546	12,203	657
Field Laboratory Operations	---	---	143,251	152,374	137,212	-15,162
Budget Authority	---	---	143,251	152,374	137,212	-15,162
FTE	**3,939**	**3,766**	**4,024**	**4,024**	**3,781**	**-243**

Figure 14 – Human Foods Funding History Table

The FY 2026 Budget for the Human Foods Program (HFP) is a total $1,250,194,000 of which $1,236,788,000 is budget authority and $13,406,000 is user fees. The budget authority increases by $65,469,000 as compared to the FY 2025 Enacted Budget; user fees increase by $721,000. The amount in the request for the HFP Center funding is $649,853,000, Field Laboratory Operations is $137,212,000 and for the Office of Inspections and Investigations (OII) is $463,129,000.

The FY 2026 Budget reflects the Administration's ongoing commitment to enhancing food safety and nutrition through the continuation of funding for several of FDA's key initiatives and program areas. This will enable FDA to better ensure the safety of the U.S. food supply by investing in programs to address nutrition and unsafe food additives, infant formula

contamination and shortages, strengthening laboratory operations, and expanding state agreements for routine inspections.

BUDGET AUTHORITY

FY 2026 President's Budget: Human Foods *Budget Authority - Dollars in Thousands*				
	Center	**Field**	**Field Lab**	**Total**
FY 2025 Enacted:	**576,058**	**442,887**	**152,374**	**1,171,319**
FY 2026 Budget Authority Changes	**72,592**	**8,039**	**(15,162)**	**65,469**
HFP MAHA	**155,784**	**72,000**	**6,843**	**234,627**
Consolidation to Core Functions	**(83,192)**	**(63,961)**	**(22,005)**	**(169,158)**
Contract Efficiencies	3,763	(21,473)	4,909	(12,801)
Reduction of the Federal Bureaucracy	(86,955)	(42,488)	(26,914)	(156,357)
FY 2026 Budget Net Total: Human Foods	**648,650**	**450,926**	**137,212**	**1,236,788**

Figure 15 – Human Foods Budget Authority

Total Budget Authority Changes +$65.5 million / -239 FTE

HFP MAHA: +$234.6 million / +295 FTE

Center: +$155.8 million / +156 FTE

Field: +$72.0 million / +139 FTE

Field Lab Ops: +$6.8 million

The FY 2026 Budget provides $234.6 million to support the Secretary's MAHA agenda by restoring trust in our food system, prioritizing public health, and strengthening nutrition and food safety. This includes $155.8 million to the HFP Center, $72.0 million to the HFP Field, and $6.8 million to HFP Field Laboratory Operations.

Address Unsafe Additives in Our Food Supply (+$48.9 million, +70 FTE)

The Budget includes $48.9 million to combat risks in the food supply by addressing unsafe chemical additives used in food and restoring public confidence in FDA's ability to transparently protect food safety. This funding would enable FDA to assess the safety of exposure to chemicals in the food supply, including meaningfully exploring closing the Generally Recognized as Safe (GRAS) loophole and more quickly implementing a framework for proactive, systematic reassessment of chemicals used in food, including initiating a first round of safety reviews of chemicals that are a top concern for consumers.

In addition, FDA would expand Closer to Zero efforts to eliminate toxic elements such as arsenic from foods consumed by infants and young children. This includes researching additional commodities and chemical hazards, monitoring and updating action levels, and continuously developing new and improved testing methods for toxic elements in food. These actions are vital to ensuring food sold in the United States is safe, particularly for vulnerable populations.

Invest in Nutrition to Combat the Chronic Disease Crisis (+$33.5 million / +13 FTE)

This funding includes $33.5 million to address the enormous chronic disease crisis in the United States, which is estimated to cost the country over $1.0 trillion annually in healthcare costs and reduces the quality of life. The proposal would support improvement in the American diet through a stronger nutrition program including providing new forms of nutrition labeling to better inform consumers about the foods they consume and incentivizing industry to manufacture healthier food. Addressing chronic disease is a top public health priority. FDA is committed to radical transparency to give Americans authentic, informed consent about what food ingredients they are eating and their effects – in alignment with both MAHA and FDA's mission.

FDA will expand a new $20.0 million pilot grant program to help schools transition to healthier foods to ensure the children of our nation are served nutritious, wholesome food that will set them up for a healthy future. School-age children continue to under consume fruits, vegetables, whole grains, and dairy and overconsume ultra-processed foods with large amounts of added sugars and sodium. The grants will support schools in acquiring the kitchen equipment and facilities needed to offer scratch-cooked meals instead of convenience and ultra-processed foods, as well as procuring more local, whole foods like fresh produce. FDA aims to drive systemic change in how Americans understand and engage with nutrition, contributing to a healthier population and a more sustainable healthcare system.

Strengthen Food Safety (+$97.8 million / +190 FTE)

This Budget includes $97.8 million to strengthen food safety. This funding would directly address inspecting high-risk facilities, strengthening import oversight, reducing foodborne disease outbreak response times, and decreasing the number of associated illnesses. It would also support advancements in technology to rapidly identify and combat foodborne pathogens. This funding is crucial to a more responsive, gold standard science-driven, and resilient food safety system capable of protecting American consumers from preventable harm.

Address Infant Formula Contaminations and Shortages (+$14.7 million, +22 FTE)

The Budget includes $14.7 million to ensure the ongoing quality, safety, nutritional adequacy, and resilience of the domestic infant formula supply. With this investment, FDA will continue to modernize infant formula oversight by enhancing surveillance systems and monitoring of adverse events, supporting innovation in ingredients and production technology, working with other agencies to support research on infant feeding, and ensuring rapid response capabilities in the event of contamination or supply disruptions. FDA remains committed to the safety, nutritional quality, and availability of infant formula and is taking decisive actions to ensure the U.S. infant formula supply ranks among the best and most trusted in the world.

Laboratory Operations Funding (+$6.8 million / 0 FTE)

The request of $6.8 million included in this initiative to support laboratory analysis is critical to the surveillance of the food supply. This investment is essential given the program's pivotal role in ensuring post-market food safety. Additional funding is critical to support laboratory capabilities to safeguard the food supply and fulfill the FDA and MAHA public health mission.

Transition Routine Food Safety Inspections (+$33.0 million / 0 FTE)

The request includes $33.0 million for FDA to expand current state agreements for routine inspections of domestic food facilities to cover all applicable domestic facilities, to the extent feasible. This paradigm shift streamlines routine inspections through a transformative oversight model that fosters enhanced collaboration between federal and state agencies and reduces redundancy. FDA has clear authority to engage states in food safety oversight and already does so effectively through established mechanisms such as cooperative agreement programs, food inspection contracts, and partnership agreements. Under this new model, domestic routine food safety screening inspections would be carried out by state agencies that maintain FDA's rigorous national standards, while FDA would focus its resources on international and high-risk, complex, and targeted inspection activities. This integrated model promotes efficiency, expands inspection coverage, and strengthens public health protection. By transitioning routine inspections of domestic food facilities to state agencies, state partners can help FDA meet its domestic inspection goals while enabling FDA to focus on higher-risk commodity work, promote national consistency, and conduct increased international oversight activities. This initiative restores a previous level of enhanced state funding while serving as a significant downpayment in advancing an integrated food safety system and safeguarding the U.S. food supply.

Consolidation to Core Functions -$169.2 million / -534 FTE

Contract Efficiencies: -$12.8 million

Center: +$3.8 million

Field: -$21.5 million

Field Lab: +$4.9 million

FDA identified a total of $12.8 million in reductions for the Human Foods Program in FY 2026 through contract and spending efficiencies. Within this initiative, $21.5 million in reductions was identified in the Human Foods field operations (OII). Due to reprioritization and refocusing to core functions across the agency, HFP center and field lab functions increased by $3.8 million and $4.9 million accordingly. These adjustments will allow the Agency to focus on mission essential- operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$156.4 million / -534 FTE

Center: -$87.0 million / -308 FTE

Field: -$42.5 million / -118 FTE

Field Lab: -$27.0 million / -108 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the

Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

Within the HFP program, a total of $156.4 million (534 FTE) was reduced including $87.0 million (308 FTE) for HFP Center, $42.5 million (118 FTE) for OII and $27.0 million (108 FTE) for Field Laboratory Operations.

PROGRAM ACCOMPLISHMENTS

The following accomplishments demonstrate the Agency's delivery of its regulatory and public health responsibilities through the programs, offices, and activities which have been brought together under the HFP. Many of these programs and activities were formerly within the Center for Food Safety and Applied Nutrition (CFSAN) and the Office of Food Policy and Response (OFPR).

- In April 2025, FDA announced a series of new measures to phase out all petroleum-based synthetic dyes from the nation's food supply and fast-track the review of natural alternatives to synthetic food dyes.
- As part of the MAHA initiative, FDA embarked on Operation Stork Speed in March 2025 to ensure that U.S. infant formula products are safe and wholesome for the families and children who rely on them.
- To promote radical transparency and ensure all Americans know what is in their food, FDA is exploring potential rulemaking to revise its Substances Generally Recognized as Safe (GRAS) Final Rule and related guidance to eliminate the self-affirmed GRAS pathway.
- In January 2025, FDA issued guidance for industry on the action levels for lead in processed food intended for babies and young children. The action levels support FDA's Closer to Zero Initiative and reflect the levels of lead at which the FDA may regard the food as adulterated under the Federal Food, Drug, and Cosmetic Act.
- In January 2025, FDA published its proposal to require a front-of-package (FOP) nutrition label on most packaged foods to provide accessible, at-a-glance information to help consumers quickly and easily identify how foods can be part of a healthy diet.
- In 2024, HFP's Coordinated Outbreak Response & Evaluation (CORE) Signals Team evaluated a total of 72 events, 26 incidents were transferred to a CORE Response Team, and public advisories were issued for 10 investigations. Public advisories issued by CORE provide specific, actionable steps for consumers to take to protect themselves.

PERFORMANCE

The Human 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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
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 2023: 50% Target: 80% (Target Not Met)	80%	80%	Maintain
214101: Number of state, local, and tribal regulatory agencies in the U.S. and its Territories enrolled in the draft Voluntary National Retail Food Regulatory Program Standards. (Outcome)	FY 2023: 959 enrolled Target: 927 (Target Exceeded)	989	1,004	15
212415: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Shiga toxin-producing Escherichia coli (STEC) infections. (Outcome)	CY 2023: 5.3 cases/100,000 Target: 4.3 (Target Not Met)	4.1	4.0	-0.1
212416: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired Listeria monocytogenes infections. (Outcome)	CY 2023: 0.31 cases/100,000 Target: 0.25 (Target Not Met)	0.25	0.25	Maintain
212417: Foodborne Illness - Reduce the incidence of laboratory-diagnosed, domestically-acquired *Salmonella* infections. (Outcome)	CY 2023: 14.2 cases/100,000 Target: 14.0 (Target Not Met but Improved)	13.4	13.1	-0.3
214337: Accuracy rate for confirmation of presumptive STEC positives from leafy green samples. (Output)	FY 2023 : 40% Target: 40% (Target Met)	60%	70%	10

Figure 16 - Foods Performance Table

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

Food Additive and Color Additive Petition Review

The Human Foods Program conducts an extensive review as part of its Food Additive and Color Additive Petition review process, which includes a Chemistry, Toxicology, and Environmental evaluation. The current measure is for FDA to complete review and action on the safety evaluation of direct and indirect food and color additive petitions within 360 days of receipt. FDA did not meet the target in FY 2023, completing 50 percent of the petitions within 360 days of receipt. Delayed review times for petitions in FY 2023 are due to increased complexity of

recent submissions that lead to additional time needed to review larger and more complex data sets. Additionally, except for environmental scientists, the staff responsible for reviewing and managing petitions also oversee other premarket review programs which are experiencing an increase in review volume and have stricter timeframes for completion. Despite the factors that led to not meeting the FY 2023 target, recent hiring efforts will facilitate the return to previous review levels. FDA will maintain FY 2025 and FY 2026 targets at 80 percent and monitor the potential need to adjust going forward.

Key Pathogens

FDA is tracking a set of performance measures related to the incidence rates of infection for Shiga toxin-producing *E. coli* (STEC), *Salmonella*, and *Listeria monocytogenes*. These organisms remain significant from a public health perspective in terms of the number and severity of illnesses they cause, and outbreaks are frequently attributed to FDA-regulated products. Therefore, there is a continued need to invest resources into prevention activities to reduce illness caused by these pathogens. In CY 2020, there was a significant decrease in the incidence rate of infection for each of these three pathogens. According to the CDC, there was a 26 percent decrease in incidence of infections caused by all pathogens transmitted commonly through food during 2020, which was the largest single-year variation in incidence during 25 years of FoodNet surveillance.[1] Widespread public health interventions implemented to prevent SARS-CoV-2 transmission might have contributed to this decrease in detection of illnesses. During 2023, the incidence and percentage of infections diagnosed by culture-independent diagnostic tests (CIDTs) reported to FoodNet continued to increase, and the percentage of cases that yielded an isolate decreased, affecting observed trends in incidence. Because CIDTs allow for diagnosis of infections that previously would have gone undetected, lack of progress toward disease reduction goals might reflect changing diagnostic practices rather than an actual increase in incidence. Continued surveillance is needed to monitor the impact of changing diagnostic practices on disease trends, and targeted prevention efforts are needed to meet disease reduction goals.[2] HFP is keeping the FY 2025 and 2026 targets in place consistent with planned progress and will monitor the potential need to adjust targets going forward.

[1] 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

[2] Hazel J. Shah, MPH, Rachel H. Jarvis, MPH, et al. Reported Incidence of Infections Caused by Pathogens Transmitted Commonly Through Food: Impact of Increased Use of Culture-Independent Diagnostic Tests — Foodborne Diseases Active Surveillance Network, 1996–2023. MMWR Morb Mortal Wkly Rep. July 4, 2024 / 73(26);584–593. DOI: http://dx.doi.org/10.15585/mmwr.mm7326a1.

HUMAN DRUGS

PROGRAM DESCRIPTION

FDA's Human Drugs Program and the Center for Drug Evaluation Review (CDER) is responsible for:

- Ensuring the safety and efficacy of prescription and over the counter (OTC) drug products, including generic drugs, and therapeutic biological products.
- Monitoring the safety of marketed drugs.
- Overseeing drug quality to prevent and detect substandard or counterfeit drugs in the U.S. market.

FDA's Human Drugs Program conducts key work to improve the review process though modernization, expediting patient access to safe and effective medications. This includes forward-looking initiatives like the FRAME initiative, which supports the adoption of advanced manufacturing technologies and strategic use of data. CDER continues to uphold and enhance gold-standards to prevent medication errors and promote the safe use of pharmaceuticals.

CDER advances strategic efforts to ensure human drugs are safe, effective, and accessible. This includes supporting rare disease drug development, enhancing drug safety oversight, ensuring the quality of compounded drugs, and addressing substance abuse and overdose prevention.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Human Drugs	**2,058,404**	**2,239,290**	**2,338,496**	**2,428,505**	**2,368,131**	**-60,374**
Budget Authority	***706,524***	***760,724***	***719,679***	***724,168***	***593,618***	***-130,550***
User Fees	***1,351,880***	***1,478,566***	***1,618,817***	***1,704,337***	***1,774,513***	***70,176***
Center	1,803,931	1,957,974	2,069,312	2,152,251	2,143,968	-8,283
Budget Authority	518,116	550,544	520,649	521,040	445,400	-75,640
User Fees	1,285,815	1,407,430	1,548,663	1,631,211	1,698,568	67,357
Field	254,473	281,316	235,427	238,320	207,256	-31,064
Budget Authority	188,408	210,180	165,273	165,194	131,311	-33,883
User Fees	66,065	71,136	70,154	73,126	75,945	2,819
Field Laboratory Operations	---	---	33,757	37,934	16,907	-21,027
Budget Authority	---	---	33,757	37,934	16,907	-21,027
FTE	**6,743**	**7,034**	**7,542**	**8,057**	**6,858**	**-1,199**

Figure 17 - Human Drugs Funding History Table

The FY 2026 Budget for the Human Drugs Program is $2,368,131,000, of which $593,618,000 is budget authority and $1,774,513,000 is user fees. The budget authority decreases by $130,550,000 compared to the FY 2025 Enacted Budget; user fees increase by $70,176,000. The amount requested for Center for Drug Evaluation and Research (CDER) is $2,143,968,000. The Office of Inspection and Investigations (OII) amount is $207,256,000 and the Field Laboratory Operations amount is $16,907,000.

The FY 2026 Budget will enable FDA to continue to carry out rigorous science-based premarket drug reviews. These efforts accompanied by the necessary funding will allow the FDA to further its 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 accessible to patients. CDER relies on high quality, evidence-based research to make regulatory decisions. 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.

BUDGET AUTHORITY

FY 2026 President's Budget: Human Drugs *Budget Authority - Dollars in Thousands*				
	Center	**Field**	**Field Lab**	**Total**
FY 2025 Enacted:	**521,040**	**165,194**	**37,934**	**724,168**
FY 2026 Budget Authority Changes	**(75,640)**	**(33,883)**	**(21,027)**	**(130,550)**
Consolidation to Core Functions	**(75,640)**	**(33,883)**	**(21,027)**	**(130,550)**
Contract Efficiencies	(20,813)	(20,666)	(230)	(41,709)
Reduction of the Federal Bureaucracy	(54,827)	(13,217)	(20,797)	(88,841)
FY 2026 Budget Net Total: Human Drugs	**445,400**	**131,311**	**16,907**	**593,618**

Figure 18 - Human Drugs Budget Authority

Total Budget Authority Changes: -$130.5 million / -337 FTE

Consolidation to Core Functions: -$130.5 million / -337 FTE

Contract Efficiencies: -$41.7 million

Center: -$20.8 million

Field: -$20.7 million

Field Lab: -$230,000

FDA identified a total of $41.7 million in reductions for the Human Drugs Program in FY 2026 through contract and spending efficiencies. Within this initiative, the reductions include $20.8 million for CDER, $20.7 million for OII and $230,000 for Field Laboratory Operations. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$88.8 million / -337 FTE

Center: -$54.8 million / -228 FTE

Field: -$13.2 million / -26 FTE

Field Lab: -$20.8 million / -83 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the

Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

Within the Drugs Program, a total of $88.8 million (337 FTE) was reduced including $54.8 million (228 FTE) for CDER, $13.2 million (26 FTE) for OII and $20.8 million (83 FTE) for Field Laboratory Operations.

USER FEES

Current Law User Fees: +$70.2 million

Center: +$67.4 million

Field: +$2.8 million

The Human Drugs Program request includes an increase of $70.2 million for user fees, compared to FY 2025 President's Budget, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM ACCOMPLISHMENTS

The FDA's Human Drug Program plays a critical role in advancing the Agency's public health mission and the HHS Secretary's Make America Health Again (MAHA) agenda. The program achieved significant milestones that enhanced the safety, effectiveness, and availability of human drugs. Below are key program accomplishments:

- In July 2024, CDER and CBER announced the Rare Disease Innovation Hub (RDIH). In CDER, the RDIH will leverage the success and activities of the Accelerating Rare disease Cures (ARC) Program.
- CDER approved 50 novel drugs in 2024, of which 26 received orphan drug designation because they target rare diseases.
- In FY 2024, FDA’s compounding program conducted 36 inspections, issued 6 warning letters and 10 referral letters to state agencies, and oversaw 31 recalls.
- In FY 2024, CDER published 13 guidances, 9 of which focused on disease-specific areas of drug development in pediatric and adult populations, including the first draft guidance on designing clinical trials for drugs to treat stimulant-use disorders.
- There were 11 new shortages in CY 2024. However, using a range of available tools, including regulatory flexibility and discretion, FDA worked with manufacturers to successfully prevent 268 shortages. Actions taken in CY 2024 to help prevent or mitigate shortages included expedited review of 206 submissions and prioritization of 20 inspections.
- CDER’s full approval list for 2024 and 2025 are available on its website.

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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
223210: Review and act on 90 percent of standard NME NDA and original BLA submissions within 10 months of the 60-day filing date. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
223211: Review and act on 90 percent of priority NME NDA and original BLA submissions within 6 months of the 60-day filing date. (Output)	FY 2022: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
223212: Review and act on 90 percent of standard non-NME original NDA submissions within 10 months of receipt. (Output)	FY 2022: 98% Target: 90% (Target Exceeded)	90%	90%	Maintain
223213: Review and act on 90 percent of priority non-NME original NDA submissions within 6 months of receipt. (Output)	FY 2022: 91% Target: 90% (Target Exceeded)	90%	90%	Maintain
223216: Review and act on 90 percent of priority original Abbreviated New Drug Application (ANDA) submissions within 8 months of receipt. (Output)	FY 2022: 95% Target: 90% (Target Exceeded)	90%	90%	Maintain
223235: Review and act on 90 percent of standard original Abbreviated New Drug Application (ANDA) submissions within 10 months of receipt. (Output)	FY 2022: 93% Target: 90% (Target Exceeded)	90%	90%	Maintain
292203: Number of medical product analyses conducted through FDA's Sentinel Initiative. (Output)	FY 2023: 65 Target: 65 (Target Met)	65	50	-15

Figure 19 - Human Drugs Performance Table

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

Review Goals

New Drug Review

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

BIOLOGICS

PROGRAM DESCRIPTION

The Center of Biologics Evaluation and Research's (CBER) mission is to ensure the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cell, tissue, 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 traces its roots to the Biologics Program in the Department of Treasury's Hygienic Laboratory, which was established alongside the passage of the Biologics Control Act of 1902.

CBER helps bring novel products to market by expediting the development and evaluation of new biological products for a broad range of diseases, including infectious diseases and complex, life-threatening, and rare diseases. The increasing sophistication and complexity of biological products requires scientific and regulatory expertise to facilitate innovation and prevent unintended harm. FDA protects the public health by using effective and smart regulation to make decisions based on a rigorous evaluation of current data and scientific evidence.

Blood products are critical to public health and offer potentially life-saving benefits for a variety of acute and chronic conditions. CBER works closely with other parts of HHS to identify and respond to potential threats to blood safety; to develop safety recommendations; to monitor the blood supply and help promote the importance of blood donation; and to collaborate with other government and nongovernment partners in ensuring an adequate supply of safe and effective, blood products.

Rare diseases affect more than 30 million people in the United States, and about half are children. Many of these rare conditions are life threatening, and most do not have approved treatments. FDA is committed to help foster the development of new and innovative medical products to treat rare diseases that were previously considered incurable. CBER's Rare Disease Program has a longstanding history of regulating and advancing the development of biological products for use in rare diseases and conditions and continues to advance the development of new and innovative biological products, such as cell and gene therapy products.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Biologics	**459,405**	**512,398**	**571,811**	**607,060**	**562,544**	**-44,516**
Budget Authority	***259,935***	***272,209***	***268,068***	***268,197***	***204,985***	***-63,212***
User Fees	***199,470***	***240,189***	***303,743***	***338,863***	***357,559***	***18,696***
Center	414,302	464,354	525,350	560,268	522,798	-37,470
Budget Authority	215,120	224,165	224,047	224,144	168,110	-56,034
User Fees	199,182	240,189	301,303	336,124	354,688	18,564
Field	45,103	48,044	46,216	46,547	39,654	-6,893
Budget Authority	44,815	48,044	43,776	43,808	36,783	-7,025
User Fees	288	---	2,440	2,739	2,871	132
Field Laboratory Operations	---	---	245	245	92	-153
Budget Authority	---	---	245	245	92	-153
FTE	**1,551**	**1,565**	**1,641**	**1,730**	**1,470**	**-260**

Figure 20 – Biologics Funding History Table

The FY 2026 Budget for the Biologics Program is $562,544,000 of which $204,985,000 is budget authority and $357,559,000 is user fees. The budget authority decreases by $63,212,000 compared to the FY 2025 Enacted Budget; and user fees increase by $18,696,000. The CBER total amount is $522,798,000. The Office of Inspection and Investigations (OII) total amount is $39,654,000 and the Field Laboratory Operations total amount is $92,000.

The FY 2026 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, tissue, and gene therapies to the American public. CBER facilitates the development and availability of safe and effective medical products by integrating 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.

BUDGET AUTHORITY

FY 2026 President's Budget: Biologics *Budget Authority - Dollars in Thousands*				
	Center	**Field**	**Field Lab**	**Total**
FY 2025 Enacted:	**224,144**	**43,808**	**245**	**268,197**
FY 2026 Budget Authority Changes	**(56,034)**	**(7,025)**	**(153)**	**(63,212)**
Consolidation to Core Functions	**(56,034)**	**(7,025)**	**(153)**	**(63,212)**
Contract Efficiencies	(27,546)	(2,017)	(1)	(29,564)
Reduction of the Federal Bureaucracy	(28,488)	(5,008)	(152)	(33,648)
FY 2026 Budget Net Total: Biologics	**168,110**	**36,783**	**92**	**204,985**

Figure 21 – Biologics Budget Authority

Total Budget Authority Changes: -$63.2 million / -112 FTE

Consolidation to Core Functions: -$63.2 million / -112 FTE

Contract Efficiencies: -$29.6 million

Center: -$27.5 million

Field: -$2.0 million

Field Lab: -$1,000

FDA identified a total of $29.6 million in reductions for the Biologics Program in FY 2026 through contract and spending efficiencies. Within this initiative, the reductions include $27.5 million for CBER Center, $2.0 million for OII and $1,000 for Field Laboratory Operations. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$33.6 million / -112 FTE

Center: -$28.5 million / -111 FTE

Field: -$5.0 million / -1 FTE

Field Lab: -$152,000 / 0 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

Within the Biologics Program, a total of $33.6 million (112 FTE) was reduced including $28.5 million (111 FTE) for CBER, $5.0 million (1 FTE) for OII and $152,000 (0 FTE) for Field Laboratory Operations.

USER FEES

Current Law User Fees: +$18.7 million

Center: +$18.6 million

Field: +$132,000

The Biologics Program request includes an increase of $18.7 million for user fees, compared to FY 2025 Enacted Budget, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM ACCOMPLISHMENTS

CBER's 2021-2025 strategic plan outlines the goals, objectives, and strategies designed to further its mission and vision during the term of the strategic plan. The plan aligns with

Department of Health and Human Services (HHS) priorities, FDA priorities, and new authorities provided through the 21st Century Cures Act and Food and Drug Omnibus Reform Act of 2022. The following selected accomplishments by priority area demonstrate the Biologics Program's delivery of its regulatory and public health responsibilities through medical product review.

- In March 2024, CBER licensed the first test intended to screen blood donations for malaria, a transfusion-transmitted infection.
- Collaborated with CDER in launching the Rare Disease Innovation Hub, Rare Disease Endpoint Advancement (RDEA) Pilot Program and Support for clinical Trials Advancing Rare disease Therapeutics (START) Pilot Program.
- CBER's Rare Disease Program continues to advance the development of new and innovative biological products; as of September 2024, CBER granted 74 Breakthrough Therapy designations, with 31 of the products having Orphan Drug Designation.
- From May 2023-May 2024, FDA approved three vaccines for adults to prevent of lower respiratory track disease caused by respiratory syncytial virus (RSV) in individuals 60 years of age and older.
- In CY 2023, CBER documented one resolved shortage, 22 new product shortages, 12 prevented shortages, four ongoing shortages, and 67 notifications from 27 different manufacturers.
- CBER's full approval list for 2024 and 2025 are available on its website.

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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
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 2023: 100% Target 90% (Target Exceeded)	90%	90%	Maintain
233208: Review and act on priority NME NDA and original BLA submissions within	FY 2023: 91% Target 90% (Target Exceeded)	90%	90%	Maintain

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
6 months of the 60-day filing date. (Output)				
233205: Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (Output)	FY 2023: 100% Target 90% (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 2022: 99% Target: 90% (Target Exceeded)	90%	90%	Maintain
233211: Review and act on new non-user fee, non-blood product applications within 12 months of receipt. (Output)	FY 2023: No applications received	60%	60%	Maintain
234101: Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2023: Continued evaluation of new methods to produce high-yield influenza vaccine reference strains. (Target Met)	Continue evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes	Continue evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes	Maintain
231301: Percentage of Lot Distribution Reports that were entered into the Regulatory Management System - Biologics License Applications	FY 2023: 95% Target 85% (Target Exceeded)	85%	85%	Maintain

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
(RMS-BLA) within 7 Days. (Output)				

Figure 22 - Biologics Performance Table

ANIMAL DRUGS AND FOODS

PROGRAM DESCRIPTION

The Center for Veterinary Medicine's (CVM) mission is to protect human and animal health. Founded as a veterinary medical branch in 1952 and formally established as CVM in 1984, the Center continues to evolve to meet the growing complexity of animal and public health needs. People around the country depend on CVM to help ensure safety, quality manufacturing, effectiveness (where applicable) and accurate labeling of animal products, whether that is drugs or food for pets or for animals who may then produce food for people. CVM also aims to encourage development and broaden access to needed animal products by spurring and supporting innovation across all its regulated product categories. A One Health approach, recognizing the interconnectedness of human, animal, and environmental health, is inherent in CVM's work and responsibilities.

The products under CVM's jurisdiction touch the lives of every American every day. They support the health of our household pets, support the livestock that produce our food and contribute to our economy, address public health problems like zoonotic disease and environmental contamination, and can have broad public health impacts. CVM's core responsibilities include ensuring the safety and effectiveness of animal drugs, regulating animal food and feed additives, overseeing novel technologies such as intentional genomic alterations (IGA), and promoting antimicrobial stewardship to address resistance threats. This supports the health of food-producing and companion animals, including minor species, and enhances the availability and diversity of approved products.

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Animal Drugs and Foods	**253,877**	**275,647**	**284,483**	**281,727**	**233,765**	**-47,962**
Budget Authority	***202,538***	***230,070***	***228,574***	***228,708***	***174,919***	***-53,789***
User Fees	***51,339***	***45,577***	***55,909***	***53,019***	***58,846***	***5,827***
Center	181,072	193,305	226,648	224,051	185,752	-38,299
Budget Authority(CVM)	130,142	148,141	171,993	172,309	128,302	-44,007
User Fees	50,930	45,164	54,655	51,742	57,450	5,708
Field	72,805	82,342	46,438	46,113	38,506	-7,607
Budget Authority	72,396	81,929	45,184	44,836	37,110	-7,726
User Fees	409	413	1,254	1,277	1,396	119
Field Laboratory Operations	---	---	11,397	11,563	9,507	-2,056
Budget Authority	---	---	11,397	11,563	9,507	-2,056
FTE	**1,048**	**1,022**	**1,040**	**1,044**	**851**	**-193**

Figure 23 - Animal Drugs and Foods Funding History Table

The FY 2026 Budget for the Animal Drugs and Foods Program is $233,765,000 of which $174,919,000 is budget authority and $58,846,000 is user fees. The budget authority decreases by $53,789,000 and the user fee increased by $5,827,000 compared to the FY 2025 Enacted Budget. The Center for Veterinary Medicine (CVM) amount in the request is $128,302,000 in budget authority and $57,450,000 in user fees. The Office of Inspections and Investigations (OII) amount is $37,110,000 in budget authority and $1,396,000 in user fees. The Field Laboratory Operations amount is $9,507,000 in budget authority.

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. The FY 2026 Budget will enable CVM to continue to fulfill its responsibilities, which include:

- Ensuring the safety and effectiveness of animal drugs.
- Ensuring the safety and effectiveness of novel technologies, like intentional genomic alterations (IGAs) in animals and animal cell- and tissue-based products (ACTPs).
- Reviewing animal food additives for safety and utility.
- Ensuring animal food is safe, made under sanitary conditions, and properly labeled.
- Supporting and spurring the development of new technologies and approaches that address health needs across the human and animal health sectors.

The program will continue supporting the health of food-producing and companion animals, including minor species, and enhances the accessibility of approved products. CVM's work educating pet owners, animal producers, veterinarians, and the animal health industry helps Americans make informed decisions about their animals' health and well-being.

BUDGET AUTHORITY

FY 2026 President's Budget: Animal Drugs and Foods *Budget Authority - Dollars in Thousands*	Center	Field	Field Lab	Total
FY 2025 Enacted:	**172,309**	**44,836**	**11,563**	**228,708**
FY 2026 Budget Authority Changes	**(44,007)**	**(7,726)**	**(2,056)**	**(53,789)**
Consolidation to Core Functions	**(44,007)**	**(7,726)**	**(2,056)**	**(53,789)**
Contract Efficiencies	(6,226)	(2,064)	(69)	(8,359)
Reduction of the Federal Bureaucracy	(37,781)	(5,662)	(1,987)	(45,430)
FY 2026 Budget Net Total: Animal Drugs and Foods	**128,302**	**37,110**	**9,507**	**174,919**

Figure 24 - Animal Drugs and Foods Budget Authority

Total Budget Authority Changes: -$53.8 million / -148 FTE

Consolidation to Core Functions: -$53.8 million / -148 FTE

Contract Efficiencies: -$8.4 million

Center: -$6.2 million

Field: -$2.1 million

Field Lab: -$69,000

FDA identified a total of $8.4 million of reductions for the Animal Drugs and Foods in FY 2026 through contract and spending efficiencies. Within this initiative, the reductions include $6.2 million for CVM, $2.1 million for OII and $69,000 for Field Laboratory Operations. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$45.4 million / -148 FTE

Center: -$37.8 million / -124 FTE

Field: -$5.7 million / -16 FTE

Field Lab: -$2.0 million / -8 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

Within the Animal Drugs and Foods program, a total of $45.4 million (148 FTE) was reduced including $37.8 million (124 FTE) for CVM, $5.7 million (16 FTE) for OII and $2.0 million (8 FTE) for Field Laboratory Operations.

USER FEES

Current Law User Fees: +$5.8 million

Center: +$5.7 million

Field: +$119,000

The Animal Drugs and Foods Program request includes an increase of $5.8 million for user fees, compared to FY 2025 Enacted Budget.

PROGRAM ACCOMPLISHMENTS

The safety and availability of animal drugs, devices, and food are critical to human and animal health and our nation's economy. CVM is committed to facilitating animal and veterinary product development across the board to see more safe, novel products and products for unmet human and animal needs reach the market. CVM has a key role in evaluating genomic alterations in animals that contribute to cutting-edge human health care interventions and research, like animals that have been genetically altered to facilitate transplantation of their organs into humans, known as xenotransplantation.

The entire U.S. population depends on FDA ensuring safety, quality manufacturing, and accurate labeling of animal products, including animal drugs, food for pets, and food for livestock that are a part of the human food supply chain.

- In March 2024, CVM published a Proposed Rule on Labeling Requirements for Approved or Conditionally Approved New Animal Drug that would create a comprehensive set of regulations establishing requirements for the content and format of the labeling for prescription and over-the-counter new animal drugs, as well as new animal drugs for use in animal food.
- In June 2024, CVM published a request for applications to establish Animal and Veterinary Innovation Centers (AVICs) – long-term partnerships with academic research institutions – as part of its ongoing commitment to encourage development of innovative products to better support animal health and veterinary interventions.
- In FY 2024, with support from U.S. Department of Agriculture and academic partners, FDA issued a supplemental approval for Safe-Guard (fenbendazole) to treat gastrointestinal worms in wild quail.
- In FY 2024, CVM worked with FDA's Office of Digital Transformation (ODT) to address vulnerabilities in the Animal Drug Supply Chain by developing cost-saving solutions following ODT's Technology Modernization Action Plan and Data Modernization Action Plan.
- Throughout FY 2024, CVM partnered with offices across FDA, other parts of the Department of Health and Human Services (HHS), the Drug Enforcement Administration (DEA), and U.S. Customs Border Protection (CBP) to fight against the opioid epidemic by helping to address the illicit use of the chemical xylazine in humans, which has been found mixed with illicit drugs, like fentanyl and heroin.
- CVM's full approval list is available on its website.

PERFORMANCE

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

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
243231: Complete review and action on Non-administrative original New Animal Drug Applications (NADAs) and reactivations of such applications received during the fiscal year within 180 days. (Output)	FY 2023: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
243232: Complete review and action on Non-administrative original Abbreviated New Animal Drug Applications (ANADAs) and reactivations of such applications received during the fiscal year within 240 days. (Output)	FY 2023: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
244204: Complete review and action on warning letters within 25 working days to better safeguard U.S. consumers by alerting firms to identified deviations in order to become compliant. (Output)	FY 2023: 71% Target: 50% (Target Exceeded)	50%	50%	Maintain
244302: Respond to consumer complaints by initiating in-depth Vet-LIRN investigations within 30 days of receipt. (Output)	FY 2023: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain

Figure 25 - Animal Drugs and Foods Performance Table

DEVICES AND RADIOLOGICAL HEALTH

PROGRAM DESCRIPTION

The Medical Device Amendments of 1976 amended the Federal Food, Drug, and Cosmetic Act outlining a risk-based classification system for devices and creating the Medical Device Program. The program operates with appropriations and user fees to protect and promote the public health by assuring that U.S. patients and providers have timely and continued access to safe, effective, and high-quality medical devices, including safe radiation-emitting products. The Devices Program provides risk-based oversight, and it 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 United States depend upon.

The Center for Devices and Radiological Health (CDRH) is responsible for protecting and promoting the public health by assuring that patients and providers have safe, effective, and high-quality medical devices and safe radiation-emitting products. These devices range from simple tongue depressors to complex instruments that help save and sustain life, like programmable pacemakers with micro-chip technology. Devices also include in vitro diagnostic products, such as next generation sequencing tests, tests for 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. CDRH provides consumers, patients, their caregivers, and providers with understandable information about the products it oversees. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the United States.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Devices and Radiological Health	**734,814**	**747,520**	**791,300**	**841,316**	**883,014**	**41,698**
Budget Authority	***419,496***	***449,600***	***445,593***	***446,660***	***454,874***	***8,214***
User Fees	***315,318***	***297,920***	***345,707***	***394,656***	***428,140***	***33,484***
Center	630,627	637,872	701,761	750,408	790,381	39,973
Budget Authority	331,951	356,362	359,500	359,749	366,365	6,616
User Fees	298,676	281,510	342,261	390,659	424,016	33,357
Field	104,187	109,648	81,357	81,977	83,538	1,561
Budget Authority	87,545	93,238	77,911	77,980	79,414	1,434
User Fees	16,642	16,410	3,446	3,997	4,124	127
Field Laboratory Operations	---	---	8,182	8,931	9,095	164
Budget Authority	---	---	8,182	8,931	9,095	164
FTE	**2,457**	**2,549**	**2,540**	**2,680**	**2,219**	**-461**

Figure 26 - Devices Funding History Table

The FY 2026 Budget for the Devices Program is $883,014,000 including $454,874,000 in budget authority and $428,140,000 in user fees. The budget authority increases by $8,214,000 and increase in user fees by $33,484,000 when compared to the FY 2025 Enacted Budget. The Center for Devices and Radiological Health (CDRH) amount is $790,381,000 with a total of $366,365,000 in budget authority and $424,016,000 in user fees. The Office of Inspections and Investigations (OII) amount is $83,538,000 with a total of $79,414,000 in budget authority and $4,124,000 in user fees. The Field Laboratory Operations is $9,095,000 in budget authority.

FDA's Devices Program assures timely patient access to medical devices that are high-quality, safe, and effective. The FY 2026 Budget allows the Devices Program to continue making advances in patient safety and in the diagnosing, monitoring, and treatment provided by new devices that patients need while simultaneously enhancing safeguards. This means that Americans have access to the safest, newest, and highest quality devices they need to improve and extend their lives, which helps to improve the health care system in the United States overall.

Since 2009, the number of innovative medical devices FDA authorized for marketing each year has increased five-fold. The Devices Program has focused on efforts to improve predictability, efficiency, and transparency of FDA regulatory systems so manufacturers are able to bring novel products to Americans in a timely manner. FDA requires sufficient funding to sustain the regulatory pipeline for medical devices that transform patients' lives for the better.

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.

BUDGET AUTHORITY

FY 2026 President's Budget: Devices and Radiological Health *Budget Authority - Dollars in Thousands*	Center	Field	Field Lab	Total
FY 2025 Enacted:	**359,749**	**77,980**	**8,931**	**446,660**
FY 2026 Budget Authority Changes	**6,616**	**1,434**	**164**	**8,214**
Devices Program	**102,161**	**15,069**	**979**	**118,209**
Consolidation to Core Functions	**(95,545)**	**(13,635)**	**(815)**	**(109,995)**
Contract Efficiencies	(22,160)	(3,590)	(54)	(25,804)
Reduction of the Federal Bureaucracy	(73,385)	(10,045)	(761)	(84,191)
FY 2026 Budget Net Total: Devices and Radiological Healt	**366,365**	**79,414**	**9,095**	**454,874**

Figure 27 - Devices Budget Authority

Total Budget Authority Changes: +8.2 million / -260 FTE

Devices Program: +$118.2 million

Center: +$102.2 million

Field: +$15.1 million

Field Lab: +$979,000

The FY 2026 Budget includes $118.2 million in budget authority to fund the anticipated increases for Advancing Medical Product Safety in the Devices Program. This represents $8.2 million request above FY 2025 levels with the remaining $110.0 million coming from existing funding within the program. This ensures the Devices Program remains at a level that allows FDA to continue collecting and spending user fee funding necessary to review new medical devices. This program supports the Secretary's MAHA agenda by ensuring access to safe, effective technologies that prevent, diagnose, and treat disease.

The Devices Program drives innovation to empower healthcare providers, support healthier outcomes for patients, and meet the mission to create a stronger, more resilient public health system. Many CDRH-reviewed devices directly support chronic disease management, reducing hospitalizations, and enabling earlier interventions. In the fight against the U.S. chronic disease epidemic, these tools will be vital to ensuring patients understand what is going on in their bodies and are able to make informed decisions about their health. These fees help FDA increase the efficiency of regulatory processes and reduce it takes to bring safe and effective medical devices to the U.S. market. Within this initiative, $102.2 million is provided for CDRH, $15.1 million for OII and $979,000 for Field Laboratory Operations.

Consolidation to Core Functions: -$110.0 million / -260 FTE

Contract Efficiencies: -$25.8 million

Center: -$22.2 million

Field: -$3.6 million

Field Lab: -$54,000

FDA identified a total of $25.8 million of contract and spending efficiencies in the Devices Program for FY 2026. Within this initiative, these include $22.2 million in CDRH, $3.6 million for OII and $54,000 for Field Laboratory Operations. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$84.2 million / -260 FTE

Center: -$73.4 million / -213 FTE

Field: -$10.0 million / -28 FTE

Field Lab: -$761,000 / -19 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health. Within the Devices Program, a total of $84.2 million (260 FTE) was reduced including $73.4 million (213 FTE) for CDRH, $10.0 million (28 FTE) for OII and $761,000 (19 FTE) for Field Laboratory Operations.

USER FEES

Current Law User Fees: +$33.5 million

Center: +$33.4 million

Field: +$127,000

The Devices Program request includes an increase of $33.5 million for user fees, compared to the FY 2025 Enacted Budget, 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 ACCOMPLISHMENTS

There are approximately 260,000 different types of medical devices on the U.S. market, manufactured in more than 27,000 facilities worldwide. FDA's Center for Devices and Radiological Health (CDRH) handles over 20,000 submissions each year, conducts numerous in-person meetings, and responds to requests for support with regulatory submissions. It also reviews medical device reports identifying adverse events, device corrections, and removals. This is all while promoting access, enhancing safety, and advancing innovation. These efforts are crucial to the U.S. supply chain, national security, and the U.S. health care system.

- CDRH granted Breakthrough Device designation to over 160 devices and granting marketing authorization to 40 Breakthrough Devices in FY 2024.

- In FY 2024, FDA worked with major online vendors to prevent the sale of thousands of unsafe and noncompliant radiation-emitting electronic products, such as high-powered lasers that lack basic safety features and noncompliant handheld diagnostic x-ray systems.
- Conducted timely review of more than 3 million medical device adverse event reports received in FY 2024.
- In November 2024, FDA announced a pilot to improve the timeliness of communications about corrective actions being taken by companies that the FDA believes are likely to be high risk recalls.
- CDRH's full approval list for 2024 is available on its website.

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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
253233: Percentage of received Original PMA, Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 days. (Outcome)	FY 2021: 73.9% Target: 90% (Target Not Met)	90%	90%	Maintain
253234: Percentage of 180-day PMA supplements reviewed and decided upon within 180 days. (Outcome)	FY 2021: 89.2% Target: 95% (Target Not Met)	95%	95%	Maintain
253235: Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days. (Outcome)	FY 2021: 89% Target: 95% (Target Not Met)	95%	95%	Maintain
253208: Percentage of De Novo requests (petitions to classify novel devices of low to moderate risk) reviewed and classified within 150 days. (Output)	FY 2020: 62.5% Target: 60% (Target Exceeded)	70%	70%	Maintain
252223: Percent of total received High Priority MDRs (Code Blue and Death adverse	FY 2023: 96.7% Target: 86% (Target Exceeded)	90%	90%	Maintain

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
events) reviewed within 10 days during the year. (Output)				
254203: Percentage of time CDRH meets the targeted deadlines for on-time recall classification (Output)	FY 2023: 99% Target: 85% (Target Exceeded)	85%	85%	Maintain
253207: Number of technical reviews of new applications and data supporting requests for premarket approvals. (Output)	FY 2023: 2,150 Target: 2,000 (Target Exceeded)	1,500	1,500	Maintain
254101: Percentage of an estimated 8,700 domestic mammography facilities that meet inspection standards, with less than 3% with Level I (serious) problems. (Outcome)	FY 2023: 98.9% Target: 97% (Target Exceeded)	97%	97%	Maintain

Figure 28 - Devices and Radiological Health Performance Table

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

Premarket Device Review

FDA is committed to protecting and promoting public health by providing timely access to safe and effective medical devices. The unprecedented COVID-19 public health emergency from FY 2020 through FY 2022 has impacted CDRH's ability to meet the FY 2021 PMA Original, Panel Track Supplement, 180 Day Supplement, and 510(k) goals. Throughout FY 2020 to FY 2022, FDA prioritized its COVID-19 related work to address the ongoing public health need for safe and effective medical devices. In FY 2021, the primary circumstance contributing to submissions missing a MDUFA goal was the continued shift in priorities to prioritize the review of EUAs and other activities to respond to the COVID-19 pandemic. This shifting of resources to address the unprecedented volume of EUA submissions and other aspects of the response to COVID-19 significantly impacted FDA's ability to meet MDUFA review goals.

NATIONAL CENTER FOR TOXICOLOGICAL RESEARCH

PROGRAM DESCRIPTION

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

- Support the translation of laboratory findings to clinical and regulatory applications.
- Assess novel toxicological testing strategies to assist FDA in the regulatory decision-making process, minimizing the need for animal studies.
- Conduct timely and authoritative toxicity assessments on FDA-regulated products, in close collaboration with Agency partners.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
National Center for Toxicological Research (Budget Authority)	70,482	76,901	77,790	77,740	56,307	-21,433
FTE	305	305	287	287	209	-78

Figure 29 - NCTR Funding History Table

The FY 2026 Budget Request for the National Center for Toxicological Research (NCTR) is $56,307,000 in budget authority. The amount decreased by $21,433,000 compared to the FY 2025 Enacted.

NCTR works with partners across FDA to ensure that research activities answer regulatory science questions. The results of this collaborative research inform regulatory activities that ensure the safety, efficacy, and quality of FDA-regulated products. 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 new alternative methods (NAMs) by assessing emerging toxicological testing strategies.
- Support FDA's Predictive Toxicology Roadmap and Advancing Alternative Methods work.
- Support CDER in investigating emerging drug compounding concerns to ensure safe and effective compounded drug products.

NCTR manages the FDA's Perinatal Health Center of Excellence (PHCE). The PHCE aims to fill knowledge gaps in safety, efficacy, or potential toxicity that currently exist for the

understudied perinatal period. This knowledge will strengthen the scientific basis of decision-making for FDA-regulated products used during the perinatal period. PHCE funds projects led by principal investigators from CBER, CDER, CDRH, OC, and NCTR.

BUDGET AUTHORITY

FY 2026 President's Budget: NCTR *Budget Authority - Dollars in Thousands*	
	Total
FY 2025 Enacted:	**77,740**
FY 2026 Budget Authority Changes	**(21,433)**
Consolidation to Core Functions	**(21,433)**
Contract Efficiencies	(7,966)
Reduction of the Federal Bureaucracy	(13,467)
FY 2026 Budget Net Total: NCTR	**56,307**

Figure 30 - NCTR Budget Authority

Total Budget Authority Changes: -$21.4 million / -78 FTE

Consolidation to Core Functions: -$21.4 million / -78 FTE

Contract Efficiencies: -$8.0 million

Center: -$8.0 million

FDA identified a total of $8.0 million in reductions for NCTR in FY 2026 through contract and spending efficiencies. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$13.5 million / -78 FTE

Center: -$13.5 million / -78 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health. Within this initiative, NCTR was reduced by a total of $13.5 million (78 FTEs).

PROGRAM ACCOMPLISHMENTS

NCTR conducts cutting-edge edge, gold-standard scientific research to support FDA's regulatory mission and ensure the safety of FDA-regulated products. NCTR's work supports and informs science-based decision-making across the agency, helping to identify, understand, and mitigate health risks associated with food, drugs, medical devices, and other regulated products. The

following are recent accomplishments that highlight NCTR's critical contributions to product safety:

- In collaboration with Center for Drug Evaluation and Research (CDER), NCTR researched the impact on neurodevelopmental effects of perinatal exposure to medication-assisted treatment (MAT) drugs, like buprenorphine and/or methadone.
- Developed alternative methods and biomarkers to assess product safety and reduce animal testing. FDA identified biomarkers as a Focus Area of Regulatory Science.
- NCTR's collaborative toxicological research on the safety of Brominated Vegetable Oil (BVO) informed FDA's decision to revoke its authorization in food use, findings cited in the July 2024 final rule.
- Completed research studies on microbial contamination and chemical risks in tattoo and permanent makeup inks. Findings supported FDA's October 2024 industry guidance to reduce insanitary conditions in ink manufacturing.
- In collaboration with FDA's Office of Cosmetics and Colors, NCTR evaluated health effects of Pigment Red 22 and Carbon Black in a human-relevant model to understand adverse tattoo reactions.
- In FY 2024, NCTR published 117 papers in various peer reviewed, scientific journals in close association with domestic and international partners.

For more information on NCTR research, please visit the website or the FDA-Track site.

PERFORMANCE

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

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target
263103: Conduct translational and regulatory research to advance the safety of products that FDA regulates. (Output)	FY 2023: In collaboration with CDER, NCTR identified potential safety gaps related to drug compounding procedures and addressed problems identified in relevant adverse event reports. (Target Met) FY 2023: CBER and NCTR scientists developed a human microphysiological placental barrier model and demonstrated that it can be used to effectively predict pharmacokinetic (PK)	In collaboration with CDER, provide data to address scientific knowledge gaps regarding potential neuropsychiatric risks to patients taking montelukast chronically. In collaboration with CDER and OWH, identify early signs of sex difference in adverse events during	Data from a full developmental neurotoxicity study will be presented at the Society of Toxicology's annual meeting and will be published in a manuscript detailing neurodevelopmental consequences of perinatal exposure to medication-assisted treatment (buprenorphine and methadone) for opioid use disorder.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target
	parameters. A manuscript highlighting study findings was submitted to Reproductive Toxicology in August 2023. (Target Met)	drug development using bioinformatics.	
263201: Develop science base for supporting FDA regulatory review of new and emerging technologies. (Output)	FY 2023: In collaboration with CBER, NCTR developed a testicular organoid microphysiological system (MPS) capable of supporting Zika virus infection and viral replication. A manuscript was submitted for publication in FY2023. (Target Met)	In collaboration with CDER, provide data to assist FDA in developing Guidance for Industry for the use of liver microphysiological system in drug safety evaluation.	Complete the publication of two test method standards on nanomaterial drug products through ASTM International for nanomaterial measurement, in collaboration with other agency and industry stakeholders.
262401: Develop biomarkers to assist in characterizing an individual's genetic profile in order to minimize adverse events and maximize	FY 2023: NCTR worked towards improving MRI biomarkers by developing and implementing an automated MRI image processing and analysis tool. A related publication can be found in Neurotoxicology and Teratology. (Target Met) FY 2023: NCTR characterized the development of an Alzheimer's Disease brain-chip for comparison to healthy brain-chips. (Target Met)	In collaboration with CDER, promote the development of biomarkers and elucidate pathways that may support the development of more effective therapies for Alzheimer's Disease.	Publication of a manuscript demonstrating CarcSeq's ability to assess/predict the carcinogenic impact of drug/chemical exposures using a known genotoxic lung carcinogen, thereby addressing a goal in the Predictive Toxicology Roadmap to find alternative and supplemental approaches that are more predictive and relevant to human cancer.
264101: Develop risk assessment methods and build biological dose-response models in support of food	FY 2023: Preliminary findings of the study to evaluate the virulence potential of pathogens such as Salmonella enterica using a 3D-structured tissue culture system were presented to the NCTR Science Advisory	In collaboration with CVM, characterize potential targets for anti-virulence drugs in food-producing animals.	Develop a research program and initiative related to Microplastics/Nanoplastics analysis in FDA regulated products.

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target
protection. (Output)	Board in 2023. Initial studies are promising; however, the system still requires further optimization and refinement. (Target Met)		
263104: Use new omics technologies to develop approaches that assess risk and assure the safety of products that FDA regulates. (Output)	FY 2023: In collaboration with CBER, preliminary lipidomic and ceramide data suggests that maternal obesity may impact pediatric vaccine outcomes. (Target Met)	In collaboration with CDER, develop a human liver 3D cell model and use this model for assessing drug-induced liver toxicity.	Complete field trial validation of the efficacy and acceptability of metagenomic analysis detection method(s).
263102: Develop computer-based models and infrastructure to predict the health risk of biologically active products. (Output)	FY 2023: In collaboration with Elsevier (via CRADA), NCTR scientists developed a preliminary predictive model to improve Drug Induced Liver Injury (DILI) assessment. The preliminary model utilizes in silico (computer-based) methods including, Artificial Intelligence (AI), as an alternative to animal methods. (Target Met)	Develop a preliminary database of extractable/leachable chemicals from medical devices.	Apply AI/ML to recognize safety and efficacy signals and predict the relevance of documents and their importance to pharmacovigilance.

Figure 31 – NCTR Performance Table

OFFICE OF INSPECTIONS AND INVESTIGATIONS - FIELD ACTIVITIES

PROGRAM DESCRIPTION

The FDA's Office of Inspections and Investigations (OII) is the lead office for all field operations. OII conducts rigorous, transparent, and science-based inspections and investigations, collects samples for analyses of regulated products and reviews imported products offered for entry into the United States. This allows OII to provide real-time evidence and insight essential in empowering fact-based regulatory decisions to protect public health. OII is responsible for a wide range of activities critical to FDA's public health mission, including:

- **Inspections,** to identify hazards before they escalate into public health crises.
- **Investigations,** to determine and document facts concerning consumer complaints, health fraud, product tampering, and recall compliance.
- **Import operations**, to prevent violative products from entering the U.S. market.
- **Emergency response,** ranging from shortages to contamination events, to ensure companies can safely manufacture food and drugs after natural disasters.

OII 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. This is accomplished by strengthening its network of regulatory partners and applying shared data and knowledge to surveillance and enforcement activities. In conducting inspections and investigations of the regulated industry, OII targets the products that pose the greatest risk such that American patients and consumers can have added confidence in and timely access to safe foods and medical products.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Office of Inspections and Investigations	**1,262,073**	**1,337,773**	**881,975**	**880,838**	**846,365**	**-34,473**
Budget Authority	*1,157,329*	*1,227,442*	*778,889*	*774,705*	*735,544*	*-39,161*
User Fees	*104,744*	*110,331*	*103,086*	*106,133*	*110,821*	*4,688*
FTE	**5,086**	**4,860**	**3,825**	**3,875**	**3,798**	**-77**

Figure 32 - OII Funding History Table

The FY 2026 Budget for Office of Inspections and Investigations (OII) is $846,365,000, includes $735,544,000 in budget authority and $110,821,000 in user fees. The budget authority decreases by $39,161,000 and increases by $4,688,000 in user fees compared to the FY 2025 Enacted Budget.

BUDGET AUTHORITY

FY 2026 President's Budget: Office of Inspections and Investigations *Budget Authority - Dollars in Thousands*	Field Human Foods	Field Human Drugs	Field Biologics	Field Animal Drugs & Foods	Field Devices	Field Total
FY 2025 Enacted:	**442,887**	**165,194**	**43,808**	**44,836**	**77,980**	**774,705**
FY 2026 Budget Authority Changes	**8,039**	**(33,883)**	**(7,025)**	**(7,726)**	**1,434**	**(39,161)**
HFP MAHA	**72,000**	**-**	**-**	**-**	**-**	**72,000**
Devices Program	**-**	**-**	**-**	**-**	**15,069**	**15,069**
Consolidation to Core Functions	**(63,961)**	**(33,883)**	**(7,025)**	**(7,726)**	**(13,635)**	**(126,230)**
Contract Efficiencies	(21,473)	(20,666)	(2,017)	(2,064)	(3,590)	(49,810)
Reduction of the Federal Bureaucracy	(42,488)	(13,217)	(5,008)	(5,662)	(10,045)	(76,420)
FY 2026 Budget Net Total: OII	**450,926**	**131,311**	**36,783**	**37,110**	**79,414**	**735,544**

Figure 33 - OII Budget Authority

Total Budget Authority Changes: -$39.2 million / -50 FTE

HFP MAHA: +$72.0 million / 139 FTE

Field Human Foods: +$72.0 million / 139 FTE

The FY 2026 Budget provides $234.6 million in budget authority requested increase for the Human Foods Program MAHA initiative and includes a total of $72.0 million for the OII. This allows the FDA to support the HHS Secretary's mission to tackle nutrition, physical activity, healthy lifestyles, over-reliance on medication and treatments, the effects of new technological habits, environmental impacts, and food and drug quality and safety across HHS.

Devices Program: +$15.1 million

Field Devices: +$15.1 million

The FY 2026 Budget includes $118.2 million in budget authority to fund the anticipated increases for Advancing Medical Product Safety in the Devices Program. Within this initiative, $102.2 million is provided for CDRH, $15.1 million for OII and $979,000 for Field Laboratory Operations.

This represents $8.2 million request above FY 2025 levels with the remaining $110.0 million coming from existing funding from within the program. This ensures the Devices Program remains at a level that allows FDA to continue collecting and spending user fee funding necessary to review new medical devices. This program supports the Secretary's Make America Healthy Again (MAHA) agenda by ensuring access to safe, effective technologies that prevent, diagnose, and treat disease.

The Devices Program drives innovation to empower healthcare providers, support healthier outcomes for patients, and meet the mission to create a stronger, more resilient public health system. Many CDRH-reviewed devices directly support chronic disease management, reducing hospitalizations, and enabling earlier interventions. In the fight against the U.S. chronic disease epidemic, these tools will be vital to ensuring patients understand what is going on in their bodies and are able to make informed decisions about their health. These fees help FDA increase

the efficiency of regulatory processes and reduce it takes to bring safe and effective medical devices to the U.S. market.

Consolidation to Core Functions: -$126.2 million / -189 FTE

Contract Efficiencies: -$49.8 million

Field Human Foods: -$21.5 million

Field Human Drugs: -$20.7 million

Field Biologics: -$2.0 million

Field Animal Drugs and Foods: -$2.1 million

Field Devices: -$3.6 million

FDA identified a total of $49.8 million in reductions for FDA's field program in FY 2026 through contract and spending efficiencies These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$76.4 million / -189 FTE

Field Human Foods: -$42.5 million / -118 FTE

Field Human Drugs: -$13.2 million / -26 FTE

Field Biologics: -$5.0 million / -1 FTE

Field Animal Drugs and Foods: -$5.7 million / -16 FTE

Field Devices: -$10.0 million / -28 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative including $76.4 million in the field program. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

USER FEES

Current Law User Fees: +$4.7 million

Field Human Foods: +$657,000

Field Human Drugs: +$2.8 million

Field Biologics: +$132,000

Field Animal Drugs and Foods: +$119,000

Field Devices: +$127,000

Field Center for Tobacco: +$834,000

The OII request includes an increase of $4.7 million for current law user fees authorized.

PROGRAM ACCOMPLISHMENTS

OII's most significant accomplishments from the past year are highlighted and described below:

- Continued to address the opioid crisis by prioritizing efforts to enhance analytical detection tools, establish satellite laboratories, and improve information technology (IT) infrastructure at the eight international mail facilities (IMF).
- Advanced key initiatives in medical product safety including the Foreign Unannounced Inspection Pilot (FUIP), Advanced Medical Product Manufacturing, Mutual Recognition Agreements and Regulatory Harmonization to Advance Medical Device Quality and Access.
- In FY 2024, FDA conducted 1,100 Foreign (food import) Supplier Verification Programs (FSVP) inspections
- In July 2024, CBP and FDA held a second joint operation to leverage regulatory authorities across agencies to prevent importation of violative ENDS products.
- In FY 2024, criminal investigations led to 87 arrests and more than $2.5 billion million in forfeitures, fines, and restitutions.
- FDA conducted over 15,300 inspections in 2024, including over 4,600 foreign inspections, up 86 percent from 2023.
- OII's inspections data and interactive dashboard can be found on this website.

PERFORMANCE

OII's performance measure topics such as its commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to OII regulatory impact on public health. These activities help 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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
214221: Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 98.9% Target: 80% (Target Exceeded)	65%	65%	Maintain
224221: Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 85.5% Target: 80% (Target Exceeded)	65%	65%	Maintain

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
234221: Percentage of Biologics significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 92.3% Target: 70% (Target Exceeded)	55%	55%	Maintain
254221: Percentage of Medical Device and Radiological Health significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2023: 87.3% Target: 80% (Target Exceeded)	65%	65%	Maintain
214222: Percentage of Human and Animal Food follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 76.0% Target: 65% (Target Exceeded)	50%	50%	Maintain
224222: Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 45.7% Target: 55% (Target Not Met)	40%	40%	Maintain
234222: Percentage of Biologics follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 82.4% Target: 65% (Target Exceeded)	50%	50%	Maintain
254222: Percentage of Medical Device and Radiological Health follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 73.3% Target: 65% (Target Exceeded)	50%	50%	Maintain

Measure	Year and Most Recent Result /Target for Recent Result (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
253221: Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2023: 100.0% Target: 65% (Target Exceeded)	50%	50%	Maintain
292201: Improve FDA's ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. (Output)	FY 2023: Developed 78 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participated in eleven exercises during the year. (All Targets Met or Exceeded)	Develop 60 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.	Develop 60 mapping products in support of FDA's emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.	Maintain

Figure 34 - OII Performance Table

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

OII Field Performance Measures

OII's performance goals measure topics such as FDA's commitment to follow-up on firms receiving significant inspection violations, as well as measurements related to OII 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.

IN FY 2023 OII missed one of its performance targets associated with follow-up inspections of Human and Animal Drug firms. This measure is an outcome goal, which depends on the corrective actions made by the firms to bring themselves into compliance, for which OII has no role or control. Center components may work with firms to provide them guidance and evaluate

corrective actions to help enable the firm to achieve compliance. Many violations found at a firm may take significant time and action before compliance can be reached. In some instances, firms do not come into compliance or other issues arise leading to another OAI finding upon re-inspection. While OII believes this is an important outcome measure to encourage and measure firms' corrective actions, and expects to meet the targets going forward, it is important to recognize that OII has limited ability to drive compliance, and the ultimate responsibility to comply rests with the firm itself.

FIELD LABORATORY OPERATIONS

PROGRAM DESCRIPTION

The FDA's field laboratories contribute to the Agency's mission through scientific testing on regulated products, and support of inspectional and compliance operations, as well as applied research, and support of criminal investigations. Field laboratories perform a variety of highly technical analyses to detect, identify, and quantify unapproved drugs and chemical contaminants in a vast variety of products including human and animal foods, vaping liquids, and pharmaceuticals.

This program consists of 15 laboratories strategically located across 12 locations in the United States and Puerto Rico. These laboratories play a critical role in safeguarding public health by conducting regulatory testing, screening and analysis of food, drugs, medical products, and cosmetics entering the U.S. market. Additionally, to continue oversight at key ports of entry, FDA's Satellite Laboratory Program is focused on detecting unapproved, counterfeit, and illicit drugs, including opioids. Satellite labs are currently operational in Chicago, Miami, and New York. A laboratory screening station is also active in Guam, strengthening FDA's mission to ensure the safety and integrity of imported products.

Analyses performed in the field laboratories include advanced microscopies, vibrational spectroscopies, nuclear magnetic resonance, chemical separations, mass spectrometry and food radiochemistry. Microbiological testing of foods and sterile/nonsterile medical products and whole genome sequencing (WGS) are also used for epidemiological trace-back based on genetic fingerprinting. FDA field laboratories adhere to a strict quality system and regulatory standards framework for testing obligations and are all accredited to ISO 17025:2017 standard.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Field Laboratory Operations	**---**	**---**	**204,664**	**223,939**	**186,507**	**-37,432**
Field Lab Budget Authority	*---*	*---*	***196,832***	***211,047***	***172,813***	***-38,234***
Field Lab User Fees	*---*	*---*	***7,832***	***12,892***	***13,694***	***802***
FTE	**---**	**---**	**395**	**401**	**183**	**-218**

Figure 35 – Field Laboratory Operations Funding History Table

The FY 2026 Budget for the Field Laboratory Operations Program is $186,507,000, including $172,813,000 in budget authority and $13,694,000 is user fees. The total budget authority decreases by $38,234,000 and the user fees increase by $802,000 compared to the FY 2025 Enacted Budget.

BUDGET AUTHORITY

FY 2026 President's Budget: Field Laboratory Operations *Budget Authority - Dollars in Thousands*	Field Lab Human Foods	Field Lab Human Drugs	Field Lab Biologics	Field Lab Animal Drugs & Foods	Field Lab Devices	Field Total
FY 2025 Enacted:	**152,374**	**37,934**	**245**	**11,563**	**8,931**	**211,047**
FY 2026 Budget Authority Changes	**(15,162)**	**(21,027)**	**(153)**	**(2,056)**	**164**	**(38,234)**
HFP MAHA	**6,843**	**-**	**-**	**-**	**-**	**6,843**
Devices Program	**-**	**-**	**-**	**-**	**979**	**979**
Consolidation to Core Functions	**(22,005)**	**(21,027)**	**(153)**	**(2,056)**	**(815)**	**(46,056)**
Contract Efficiencies	4,909	(230)	(1)	(69)	(54)	4,555
Reduction of the Federal Bureaucracy	(26,914)	(20,797)	(152)	(1,987)	(761)	(50,611)
FY 2026 Budget Net Total: Field Lab Operations	**137,212**	**16,907**	**92**	**9,507**	**9,095**	**172,813**

Figure 36 - Field Laboratory Operations Budget Authority

Total Budget Authority Changes: -$38.2 million / -218 FTE

HFP MAHA: +$6.8 million / +0 FTE

Field Lab Foods: +$6.8 million / 0 FTE

The FY 2026 Budget provides $234.6 million to support the Secretary's MAHA agenda by restoring trust in our food system, prioritizing public health, and strengthening national nutrition and food safety. This includes $6.8 million to HFP Field Laboratory Operations. The request of $6.8 million included in this initiative to support laboratory analysis is critical to the surveillance of the food supply. This investment is essential given the program's pivotal role in ensuring post-market food safety. Additional funding is critical to support laboratory capabilities to safeguard the food supply and fulfill the FDA and MAHA public health mission.

Devices Program: +$979,000

Field Lab Devices: +$979,000

The FY 2026 Budget includes $118.2 million in budget authority to fund the anticipated increases for Advancing Medical Product Safety in the Devices Program, including $979,000 for Field Laboratory Operations.

The total funding represents $8.2 million request above FY 2025 levels with the remaining $110.0 million coming from existing funding within the program. This ensures the Devices Program remains at a level that allows FDA to continue collecting and spending user fee funding necessary to review new medical devices. This program supports the Secretary's Make America Healthy Again (MAHA) agenda by ensuring access to safe, effective technologies that prevent, diagnose, and treat disease.

The Devices Program drives innovation to empower healthcare providers, support healthier outcomes for patients, and meet the mission to create a stronger, more resilient public health system. Many CDRH-reviewed devices directly support chronic disease management, reducing hospitalizations, and enabling earlier interventions. In the fight against the U.S. chronic disease epidemic, these tools will be vital to ensuring patients understand what is going on in their

bodies and are able to make informed decisions about their health. These fees help FDA increase the efficiency of regulatory processes and reduce it takes to bring safe and effective medical devices to the U.S. market.

Consolidation to Core Functions: -$46.1 million / -214 FTE

Contract Efficiencies: +$4.6 million

Field Lab Foods: +$4.9 million

Field Lab Drugs: -$230,000

Field Lab Biologics: -$1,000

Field Lab Animal Drugs and Foods: -$69,000

Field Lab Devices: -$54,000

FDA identified a total of $4.6 million in reductions for field laboratory operations in FY 2026 through contract and spending efficiencies. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$50.6 million / -218 FTE

Field Lab Foods: -$26.9 million / -108 FTE

Field Lab Drugs: -$20.8 million / -83 FTE

Field Lab Biologics: -$152,000 / 0 FTE

Field Lab Animal Drugs and Foods: -$2.0 million / -8 FTE

Field Lab Devices: -$761,000 / -20 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative including $50.6 million (218 FTE) for field laboratory operations. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

USER FEES

Current Law User Fees: +$802,000

Field Lab Tobacco: +$802,000

The Field Laboratory Operations activity request includes an increase of $802,000 for current law user fees authorized.

ACCOMPLISHMENTS

- Identified the bacterium *Pseudomonas aeruginosa* as the source of contamination in over-the-counter eye drops, preventing widespread health hazards.
- Developed a novel method to detect low levels of benzene, a known carcinogen, in sunscreen products.
- Provided critical analytical response to high-profile events, including outbreak/CORE (Coordinated Outbreak Response & Evaluation network), complaints and national emergencies.
- Performed scientific data reviews of private laboratory analysis that support import admissibility decisions for foods.
- 85 percent of the inspections involving laboratory scientists led to outcomes requiring corrective actions by the inspected firms, highlighting their critical contributions to maintaining and enhancing public health standards.

PERFORMANCE

Field Laboratory Operation's performance measures focus on laboratory activities 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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
214206: Maintain accreditation for OII labs. (Outcome)	FY 2023: 12 labs Target: 12 labs (Target Met)	12 labs	12 labs	Maintain
214305: Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and chemical samples/week). (Outcome)	FY 2023: 3,200 rad & 2,600 chem Target: 3,200 rad & 2,600 chem (Target Met)	3,200 rad & 2,600 chem	3,200 rad & 2,600 chem	Maintain

Figure 37 – Field Laboratory Operations Performance Table

TOBACCO CONTROL ACT

PROGRAM DESCRIPTION

The Center for Tobacco Products (CTP) oversees the implementation of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act). FDA works to protect the public health of the U.S. population from tobacco-related death and disease by comprehensively regulating the manufacture, distribution, and marketing of tobacco products; educating the public, especially youth, about the dangers of using tobacco products; and promoting and supporting strategies that ensure an equitable chance at living a healthier life for everyone.

Section 919 of the of the Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to assess user fees on tobacco products that fall within six product classes: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco. Currently, the Tobacco Control Act does not provide a means for FDA calculation and collection of user fees for electronic nicotine delivery systems (ENDS) products – more commonly referred to as e-cigarettes – and certain other deemed and novel products.

FDA executes regulatory and public health responsibilities in program areas that support the following objectives:

- Reducing initiation of tobacco product use
- Encouraging cessation among tobacco product users
- Decreasing the harms of tobacco products

Guided by the Center's strategic plan, CTP takes a comprehensive approach to reduce the negative health effects of tobacco product use. The Center develops policy, issues regulations, conducts research, educates people on tobacco products, and makes 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.

Allocation Methods: Competitive Grants; Contracts; Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Tobacco	**746,518**	**693,377**	**684,760**	**688,827**	**689,258**	**431**
User Fees	***746,518***	***693,377***	***684,760***	***688,827***	***689,258***	***431***
Center	725,178	678,103	662,061	662,487	661,282	-1,205
Field	21,340	15,274	14,867	13,448	14,282	834
Field Laboratory Operations	---	---	7,832	12,892	13,694	802
FTE	**1,259**	**1,245**	**1,311**	**1,358**	**1,047**	**-311**

Figure 38 - CTP Funding History Table

The FY 2026 Budget Request for the Tobacco Program is $689,258,000 and represents all user fees. A total of $661,282,000 is for the Center for Tobacco Products, $14,282,000 for the Office

of Inspections and Investigations (OII), and $13,694,000 for the Field Laboratory Operations. This is an increase of $431,000 above the FY 2025 Enacted Level.

CTP is participating in FDA's operational streamlining to transform the federal bureaucracy to restore accountability to the American public. It is also reducing contracts in line with the U.S. government-wide contract efficiency initiative.

PROGRAM ACCOMPLISHMENTS

The following selected accomplishments demonstrate FDA's delivery of its regulatory and public health responsibilities.

- On March 28, 2024, FDA launched a Searchable Tobacco Products Database, a user-friendly list of tobacco products – including e-cigarettes – that may be legally marketed in the United States.
- As of October 31, 2024, FDA has issued marketing denial orders (MDOs) for 1.3 million products and marketing granted orders (MGOs) for 56 products; 34 of the 56 authorized products are e-cigarette products or devices, most of which are unflavored.
- Data from the 2024 National Youth Tobacco Survey (NYTS) indicated that an estimated 2.3 million U.S. middle and high school students reported currently using tobacco products in 2024, with e-cigarettes being the most commonly used product (1.6 million students). Youth tobacco product use in the United States reached its lowest level in the NYTS' 25-year history, largely due to a drop in e-cigarette use.
- Since the inception of the Tobacco Program's manufacturer inspection activities through October 31, 2024, CTP has overseen the completion of more than 4,900 inspections of vape shops to verify whether they were engaged in manufacturing activities, and OII has completed over 2,000 routine biennial inspections of tobacco product manufacturers.
- Since the enactment of the Tobacco Control Act on June 22, 2009, through October 31, 2024, FDA has issued approximately 450 warning letters as a result of post inspectional compliance activities.
- CTP's Searchable Tobacco Products Database is available on its website.

PERFORMANCE

The Tobacco Control Act Program's performance measures focus on activities 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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
280005: Total number of compliance check inspections of retail establishments in States under contract. (Outcome)	FY 2024: 117,078 Target: 110,000 (Target Exceeded)	70,000	65,000	-5,000

280010: Number of closed applications and deficiency letters for Premarket Tobacco Product Applications (PMTA). (Output)	FY 2024: 93,025 Target: 660 (Target Exceeded)	700	700	Maintain
280011: Number of closed applications and deficiency letters for Substantial Equivalence (SE) Reports. (Output)	FY 2024: 865 Target: 550 (Target Exceeded)	600	600	Maintain
280012: Number of closed applications and deficiency letters for Exemption from Substantial Equivalence Requests (EX REQ). (Output)	FY 2024: 151 Target: 330 (Target Not Met)	290	300	Maintain
280037: Percentage of youth(12-17-year-olds) reached with campaign messages about the harmful effects of tobacco use. (Output)	FY 2024: 90% Target: 75% (Target Exceeded)	75%	70%	-5%

Figure 39 - Tobacco Control Act Performance Table

Exemption From Substantial Equivalence Requests (EX REQ)

This performance measure includes any of the following final Agency actions that result in CTP's closure of an application and applies to all tobacco product categories: Refuse to Accept (RTA); Exempt (EX); and Not Exempt (NEX). The measure also includes closure of a review cycle through issuance of a Deficiency letter (DL), or other actions. Generally, although FDA does not intend to issue DLs for EX REQs, a DL may be issued during the substantive scientific review phase and list additional information that FDA needs to complete review. As CTP has more experience, and the resources required for reviewing EX REQs are not as extensive as other pathways, the Center has been able to review and close a larger number of products than was expected. CTP's FY 2024 actuals did not meet the target of closing 330 EX REQs as fewer than 330 EX REQs were received in FY 2024 and CTP strategically reallocated resources from the EX REQ-pathway to support the increased demands of the PMTA pathway. As a result, FY 2025 and FY 2026 targets have been reduced.

Compliance Check Inspections

A key element in enforcing the Tobacco Control Act involves contracts with U.S. state, territory, and tribal agencies, as well as private entities, to conduct retailer compliance checks. FDA generally conducts over 100,000 inspections each fiscal year, except during the COVID-19 pandemic. In FY 2025 and FY 2026, FDA expects jurisdictions and private entities to continue to contract with FDA. FDA has had to make difficult resource trade-offs to reallocate or divert funding towards enforcement and compliance efforts; however, even with these efforts the Agency still expects the number of inspections conducted to decrease beginning in FY 2026 due to growing Center-wide resource constraints.

OFFICE OF THE COMMISSIONER

PROGRAM DESCRIPTION

The Office of the Commissioner (OC) provides strategic direction and a wide array of essential services to advance the FDA's mission to protect and promote public health. OC leads cross-agency initiatives in medical, scientific, and regulatory programs; offers legal counsel and litigation services; and drives agency-wide policy development to improve efficiency and consistency in alignment with federal statutes and regulations.

OC is responsible for directing policy, fostering scientific innovation, and overseeing the integrity of the global supply chain to ensure public health protection. Its work enhances supply chain transparency and accountability, strengthens enforcement tools, and promotes industry responsibility. OC also facilitates collaboration with international regulators and third-party stakeholders. In coordination with FDA Centers and Offices, OC plays a critical role to assess and strengthen preventive control standards, advance the development of predictive safety models, and accelerate the delivery of innovative cancer therapies. It leads the effort to improve methods for detecting, investigating, and preventing foodborne contamination, and to integrate pre- and post-market oversight into a comprehensive regulatory framework.

OC is committed to effective and efficient management of FDA's public health mission, delivering advanced technologies, innovative solutions, and high-quality administrative services to internal and external stakeholders preventing unsafe products from harming consumers.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Office of the Commissioner	330,985	362,527	382,849	364,043	291,318	-72,725
Budget Authority 1/	*204,250*	*221,435*	*241,304*	*234,981*	*157,099*	*-77,882*
User Fees	*126,735*	*141,092*	*141,545*	*129,062*	*134,219*	*5,157*
FTE	995	1,036	1,005	1,056	270	-786

Figure 40 – FDA OC's Funding History Table

The FY 2026 Budget for OC is $291,318,000 including $157,099,000 in budget authority and $134,219,000 in user fees. The budget authority decreases by $77,882,000 and user fees increase by $5,157,000 compared to the FY 2025 Enacted Budget.

BUDGET AUTHORITY

FY 2026 President's Budget: Office of the Commissioner *Budget Authority - Dollars in Thousands*	
	Total
FY 2025 Enacted:	**234,981**
FY 2026 Budget Authority Changes	**(77,882)**
Consolidation to Core Functions	**(77,882)**
Contract Efficiencies	(43,228)
Reduction of the Federal Bureaucracy	(34,654)
FY 2026 Budget Net Total: Office of the Commissioner	**157,099**

Figure 41 – FDA OC's Budget Authority

Total Budget Authority Changes: -$77.9 million / -471 FTE

Consolidation to Core Functions: -$77.9 million / -471 FTE

Contract Efficiencies: -$43.2 million

FDA identified a total of $43.2 million of savings for the Office of the Commissioner (OC) in FY 2026 through contract and spending efficiencies. These adjustments will allow the Agency to focus on mission-essential operations, reduce duplications, and uphold its core public health mission with greater efficiency.

Reduction of Federal Bureaucracy: -$34.7 million / -471 FTE

The FY 2026 Budget reflects a decrease of 1,940 FTEs and $456.6 million in budget authority in support of the Reduction of Federal Bureaucracy initiative, including $34.7 million (471 FTE) in OC. These reductions are part of a critical transformation of the Federal bureaucracy to restore accountability to the American public. FDA is streamlining functions and fostering innovation in workflow management to enable the Agency to shift towards a more efficient operating model. The Agency will reduce duplications and encourage cross-functional collaboration while continuing to protect and promote the public health.

USER FEES

Current Law User Fees: +$5.2 million

The FY 2026 Budget includes an increase of $5.2 million in current law user fees for OC. 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 ACCOMPLISHMENTS

The following accomplishments demonstrate OC's delivery of its regulatory and public health responsibilities within the context of current priorities.

- Spearheaded FDA-wide policy alignment on food chemical safety, antimicrobial resistance, digital health oversight, and advancing the Modernization of Cosmetics

Regulation Act of 2022 (MoCRA) – all supporting the goal to Make America Healthy Again.

- Revoked Red Dye No. 3 authorization in food and drugs due to potential carcinogenic risks in January 2025. OC set reformulation deadlines for food (January 2027) and drugs (January 2028) for manufacturers.
- Announced a plan to phase out petroleum-based synthetic dyes in the nation's food supply by the end of 2026 to reduce health risks, especially for children, in April 2025.
- Hosted the Digital Health Advisory Committee meeting to guide regulatory policy in advanced therapeutics, diagnostics, and artificial intelligence, supporting safe innovation aligned with gold standard science in November 2024.
- Led the 2024 Pediatric Advocacy Forum to strengthen collaboration and promote development of new safe and effective cancer treatments for children.
- Strengthened FDA engagement with regulatory counterparts to harmonize standards, reduce duplication, and enhance safety surveillance of imported products.
- Streamlined enterprise automation and initiatives to optimize resource allocation and increase operational efficiency in support of cost-effective agency operations, included over $200 million in future contract savings.

PERFORMANCE

The OC 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 2025 Target	FY 2026 Target	FY 2026 +/- FY 2025
291131: Percentage of scientists retained at FDA after completing Fellowship or Traineeship programs. (Outcome)	FY 2023: 55% Target: 20% (Target Exceeded)	20%	20%	Maintain
293205: Percentage of requests for combination product designations processed within the 60-day statutory requirement. (Output)	FY 2023: 100% Target: 95% (Target Exceeded)	95%	95%	Maintain
293203: Number of pediatric scientific, ethical, product, and product class issues identified through collaboration with the 27 European Union countries coordinated with the EMA, Japan, Canada, and Australia. (Output)	FY 2023: 142 Target: 100 (Target Exceeded)	100	100	Maintain

291306: The number of targeted engagements, which are strategic interactions between FDA and stakeholders that produce a tangible result in support of FDA's global mission. (Outcome)	FY 2023: 204 Target: 50 (Target Exceeded)	70	70	Maintain
291406: Percentage of invoices issued on time within predefined dates in the month. (Output)	FY 2023: 100% Target: 98% (Target Exceeded)	98%	98%	Maintain

Figure 42 - FDA OCs Performance Table

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

PROGRAM DESCRIPTION

FDA's Infrastructure Program supports the agency's lab, inspectional, investigative, and office facilities nationwide. The program covers GSA Rent; security, utilities, and maintenance operations throughout FDA's directly owned and GSA-controlled real property portfolio; and mission-support services at its headquarters White Oak Campus. Because it provides reliable, safe, and efficient work environments, the Infrastructure Program empowers 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.

FDA strategically manages its infrastructure and 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 responsibilities is communicated to the Department for inclusion in the Capital Plan that HHS submits to the Office of Management and Budget.

The Infrastructure Program consists of:

- General Services Administration (GSA) Rental Payments
- Other Rent and Rent Related Activities
- White Oak

Infrastructure investments advance strategic Administration priorities in federal stewardship, workplace modernization, and operational resilience. Reliable infrastructure underlies every aspect of FDA's regulatory, scientific, and administrative activities.

Allocation Methods: Direct Federal/Contract

BUDGET REQUEST

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
FDA White Oak Campus	**49,589**	**51,594**	**55,061**	**54,917**	**44,612**	**-10,305**
Budget Authority	*46,664*	*48,414*	*52,498*	*52,498*	*41,998*	*-10,500*
User Fees	*2,925*	*3,180*	*2,563*	*2,419*	*2,614*	*195*
Other Rent and Rent Related	**147,911**	**142,227**	**161,165**	**160,259**	**113,826**	**-46,433**
Budget Authority	*99,762*	*106,095*	*154,879*	*154,879*	*108,415*	*-46,464*
User Fees	*48,149*	*36,132*	*6,286*	*5,380*	*5,411*	*31*
GSA Rental Payments	**216,190**	**222,047**	**228,038**	**220,288**	**190,507**	**-29,781**
Budget Authority	*153,286*	*166,286*	*163,000*	*163,000*	*132,863*	*-30,137*
User Fees	*62,904*	*55,761*	*65,038*	*57,288*	*57,644*	*356*

Figure 43 – Infrastructure Funding History Table

The FY 2026 Budget for the Infrastructure Program includes a total of $283,276,000 in budget authority, a decrease of $87,101,000 from the FY 2025 Enacted Budget; and $65,669,000 in user fees, an increase of $582,000 above the FY 2025 Enacted Budget.

The decrease in budget authority reflected for GSA Rent considers the expected cost of rental payments to GSA for FDA's occupancy of approximately 6.5 million square feet of GSA-controlled 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.

BUDGET AUTHORITY

The FY 2026 Budget for the Infrastructure Program includes the following budget authority:

FY 2026 President's Budget: **Infrastructure** *Budget Authority - Dollars in Thousands*	
	Total
FY 2025 Enacted:	**370,377**
FDA White Oak Campus	52,498
Other Rent and Rent Related	154,879
GSA Rental Payments	163,000
FY 2026 Budget Authority Changes	**(87,101)**
FDA White Oak Campus	(10,500)
Other Rent and Rent Related	(46,464)
GSA Rental Payments	(30,137)
FY 2026 Budget Net Total: Infrastructure	**283,276**
FDA White Oak Campus	41,998
Other Rent and Rent Related	108,415
GSA Rental Payments	132,863

Figure 44 – Infrastructure Budget Authority

Total Budget Authority Changes: -$87.1 million

WO Campus: -$10.5 million

OR&R: -$46.5 million

GSA Rent: -$30.1 million

White Oak Campus

The FY 2026 Budget for White Oak Campus includes a total of $42.0 million in budget authority, a decrease of $10.5 million below the FY 2025 Enacted Budget.

Other Rent and Rent-Related

The FY 2026 Budget for Other Rent and Rent Related (OR&R) includes a total of $108.4 million in budget authority, a decrease of $46.5 million below the FY 2025 Enacted Budget.

GSA Rental Payments
The FY 2026 Budget for the GSA Rental Payments includes a total of $132.9 million, a decrease of $30.1 million below the FY 2025 Enacted Budget.

USER FEES

Current Law User Fees: +$582,000

WO Campus: +$195,000

OR&R: +$31,000

GSA Rent: +$356,000

The Infrastructure Program request includes a total increase of $582,000 in user fees when compared to the FY 2025 Enacted Budget.

PROGRAM ACCOMPLISHMENTS

The Infrastructure Program directly supports FDA's priorities by providing safe, secure, modern, and cost-effective laboratory, inspectional, investigative, and office 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 accomplishments include the following:

- Maintaining uninterrupted White Oak campus operations, supporting FDA staff across laboratories and headquarters offices.
- Managing utility and maintenance contracts for more than 60 GSA- and agency-owned sites nationwide, ensuring regulatory program continuity.
- Renovating an existing building to provide additional storage on the White Oak Campus to support consolidating FDA's headquarters staff and reducing FDA's real estate footprint.
- Initiating a consolidation of the Office of Criminal Investigations' headquarters in Rockville, MD, to the White Oak Campus to reduce FDA's GSA-leased footprint.
- Coordinating leasing/relocation activities for OII resident posts, border stations, district offices, and field offices to enhance inspection and criminal-investigation operations necessary to protect public health.
- Coordinating leasing, design, and construction activities required to expand OII's presence in seven International Mail Facilities, to enhance opioid interdiction efforts, and to combat the addiction crisis threatening American families.

BUILDINGS AND FACILITIES

PROGRAM DESCRIPTION

FDA's Buildings and Facilities (B&F) Program funds maintenance, repair, and critical renovations and improvements at FDA-owned laboratory sites. The program addresses deferred maintenance, modernizes outdated infrastructure, and ensures compliance with safety, accessibility, and lab standards. B&F investments are vital to sustaining scientific and regulatory operations and safeguarding mission-critical functions across FDA.

The B&F efforts support broader Administration goals to modernize federal infrastructure, enhance public health preparedness, and responsibly manage government assets. Through targeted maintenance, repairs, renovations, and improvements, FDA strengthens resilience, improves operational efficiency, and protects the federal investment in its facilities.

Allocation Methods: Direct Federal/Contract

(Dollars in Thousands)	FY 2022 Actuals	FY 2023 Actuals	FY 2024 Final	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB (+/-) FY 2025 Enacted
Buildings and Facilities (Budget Authority)	15,120	20,060	5,000	5,000	5,000	---

Figure 45- Buildings and Facilities Funding History

BUDGET REQUEST

FY 2026 President's Budget: Buildings and Facilities *Budget Authority - Dollars in Thousands*	Total
FY 2025 Enacted:	**5,000**
FY 2026 Budget Authority Changes	**-**
FY 2026 Budget Net Total: B&F	**5,000**

Figure 46 – Budget Authority

The FY 2026 Budget for Buildings and Facilities includes $5.0 million in budget authority, flat with the FY 2025 Enacted Budget.

It is essential to maintain, repair, and improve FDA's owned facilities, which primarily house laboratories. Insufficient funding over the years has caused these facilities to deteriorate to an overall poor condition, compromising FDA's ability to ensure continuity of lab operations, to recruit and retain world-class scientific staff, and to effectively execute its mission. Funding is required to begin to reverse the trend of this deterioration.

FDA must support FDA's six mission-critical, owned facilities, including the site infrastructure and buildings. FDA will continue to prioritize the most urgent and critical needs across its owned

infrastructure and facilities. In FY 2026, FDA plans to initiate the following projects, pending the availability of funding.

Gulf Coast Seafood Laboratory - Dauphin Island, Alabama

- No projects scheduled.

Jefferson Laboratories Complex (JLC) - Jefferson, Arkansas

FDA will initiate facility improvement projects to:

- Replace elevators in Building 50.
- Upgrade infrastructure in Building 62 to support mission critical lab equipment.

Muirkirk Road Complex (MRC) - Laurel, Maryland

FDA will initiate facility improvement projects to:

- Repair water heating pump infrastructure for campus.

Pacific Southwest Laboratory - Irvine, California

- No projects scheduled.

San Juan District Office and Laboratory - San Juan, Puerto Rico

- No projects scheduled.

Winchester Engineering and Analytical Center (WEAC) – Winchester, Massachusetts

- No projects scheduled.

The following table provides an allocation plan by site for use of the FY 2026 funds.

FY 2026 BUILDINGS AND FACILITIES ALLOCATION PLAN

BUILDINGS AND FACILITIES ALLOCATION PLAN FY 2026	
Site	**President's Budget**
Gulf Coast Seafood Laboratory – Dauphin Island, AL	$0
Jefferson Laboratories Complex (NCTR & Arkansas Lab) – Jefferson, AR	$2,000,000
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	$3,000,000
Pacific Laboratory SW – Irvine, CA	$0
San Juan District Office and Laboratory – San Juan, PR	$0
Winchester Engineering and Analytical Center – Winchester, MA	$0
B&F Project Total	**$5,000,000**

Figure 47 - Buildings and Facilities Allocation Plan

In FY 2026, 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 public health mission.

PROGRAM 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 lab sites 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.

The B&F objectives are tied to providing FDA's workforce with the work environments necessary to effectively evaluate and regulate medical, food, and tobacco products. The currently poor overall condition of FDA's owned buildings and facilities, especially its labs, directly affects FDA's ability to foster the scientific innovation necessary to improve healthcare, expand access to medical products, and advance public health goals. Investing in FDA's facilities will provide the high-quality infrastructure and work environment needed for FDA employees to achieve FDA's critical mission.

Program accomplishments include the following:

- Acquiring four acres of land from the U.S. Coast Guard on Dauphin Island, AL, to allow FDA to relocate lab operations from its aged and functionally obsolete existing Gulf Coast Seafood Lab on Dauphin Island to a newly constructed lab building.
- Ongoing renovation of laboratory Building 62 of the Jefferson Labs Complex in Jefferson, AR.
- Replacing failing roofs across the Jefferson Labs Complex.
- Ongoing construction of a new chiller plant for the Jefferson Labs Complex.
- Replacing the laboratory vacuum-pump system at the Pacific Southwest Laboratory in Irvine, CA.
- Initiating replacement of the Pacific Southwest Laboratory fire-alarm system.

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SUPPLEMENTAL ITEMS

OBJECT CLASS TABLES

BUDGET AUTHORITY BY OBJECT CLASS

Food and Drug Administration

Budget Authority by Object Class

(Dollars in Thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB ± FY 2025 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,195,120	1,217,082	993,824	-223,257
Other than full-time permanent (11.3)	90,124	91,780	74,944	-16,836
Other personnel compensation (11.5)	52,210	53,170	43,417	-9,753
Military Personnel - Basic Allowance for Housing (11.6)	80	80	80	---
Military personnel (11.7)	84,122	83,980	83,980	---
Special personnel services payments (11.8)	1,072	1,091	891	-200
Subtotal, Personnel Compensation	**1,422,728**	**1,447,184**	**1,197,137**	**-250,047**
Benefits:				
Civilian benefits (12.1)	491,831	500,869	408,991	-91,878
Military benefits (12.2)	8,520	8,506	8,506	---
Benefits to former personnel (13.0)	24	24	20	-4
Subtotal, Benefits	**500,374**	**509,399**	**417,516**	**-91,882**
Total Personnel Compensation and Benefits	**1,923,102**	**1,956,582**	**1,614,653**	**-341,929**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	45,986	44,953	43,774	-1,179
Transportation of things (22.0)	3,871	3,784	3,684	-99
Rental payments to GSA (23.1)	163,000	163,000	132,863	-30,137
Rent payments to others (23.2)	342	335	326	-9
Communication, utilities, and misc. charges (23.3)	12,102	11,831	11,520	-310
Printing and reproduction (24.0)	641	627	611	-16
Subtotal, Contractual Services	**225,943**	**224,529**	**192,779**	**-31,750**
Other Contractual Services:				
Consulting services (25.1)	64,212	62,770	61,124	-1,646
Other services (25.2)	296,878	290,212	282,602	-7,609
Purchase of goods and svcs from Govt Acts. (25.3)	520,073	508,395	495,065	-13,330
Operation and maintenance of facilities (25.4)	100,708	98,447	95,865	-2,581
Research and Development Contracts (25.5)	20,138	19,686	19,170	-516
Medical care (25.6)	20,562	20,101	19,574	-527
Operation and maintenance of equipment (25.7)	88,565	86,576	84,306	-2,270
Subtotal, Other Contractual Services	**1,111,136**	**1,086,186**	**1,057,706**	**-28,480**
Supplies and Materials:				
Supplies and materials (26.0)	44,047	43,058	41,929	-1,129
Equipment (31.0)	27,850	27,225	26,511	-714
Land and Structures (32.0)	35,325	34,532	33,626	-905
Grants, subsidies, and contributions (41.0)	209,005	204,312	198,955	-5,357
Insurance claims and indemnities (42.0)	565	552	537	-14
Interest and dividends , Refunds (43.0, 44.0)	---	---	---	---
Receivables-collected (61.7)	---	---	---	---
Confidential expenditures (91.0)	178	174	169	-5
Subtotal, Supplies and Materials	**316,970**	**309,852**	**301,728**	**-8,124**
Total Contractual Services and Supplies	**1,654,048**	**1,620,568**	**1,552,213**	**-68,355**
Total Budget Authority by Object Class	**3,577,150**	**3,577,150**	**3,166,866**	**-410,284**

Figure 48 - Budget Authority by Object Class

USER FEES BY OBJECT CLASS

Food and Drug Administration
User Fees by Object Class
(Dollars in Thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB ± FY 2025 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	1,140,277	1,270,199	1,021,066	-249,133
Other than full-time permanent (11.3)	107,564	119,820	96,319	-23,501
Other personnel compensation (11.5)	68,882	76,730	61,680	-15,050
Military Personnel - Basic Allowance for Housing (11.6)	21	22	22	---
Military personnel (11.7)	79,736	83,326	83,326	---
Special personnel services payments (11.8)	341	380	305	-74
Subtotal, Personnel Compensation	**1,396,820**	**1,550,475**	**1,262,717**	**-287,758**
Benefits:				
Civilian benefits (12.1)	464,087	516,965	415,569	-101,396
Military benefits (12.2)	10,775	11,260	11,260	---
Benefits to former personnel (13.0)	---	---	---	---
Subtotal, Benefits	**474,862**	**528,225**	**426,829**	**-101,396**
Total Personnel Compensation and Benefits	**1,871,682**	**2,078,700**	**1,689,546**	**-389,154**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	21,817	20,894	29,500	8,607
Transportation of things (22.0)	1,639	1,570	2,216	647
Rental payments to GSA (23.1)	65,038	57,288	57,644	356
Rent payments to others (23.2)	151	144	204	59
Communication, utilities, and misc. charges (23.3)	142	136	193	56
Printing and reproduction (24.0)	44	42	59	17
Subtotal, Contractual Services	**88,831**	**80,074**	**89,816**	**9,742**
Other Contractual Services:				
Consulting services (25.1)	179,402	171,810	242,584	70,773
Other services (25.2)	397,483	380,663	537,469	156,806
Purchase of goods and svcs from Govt Acts. (25.3)	520,986	498,939	704,466	205,527
Operation and maintenance of facilities (25.4)	6,322	6,055	8,549	2,494
Research and Development Contracts (25.5)	22,321	21,376	30,182	8,806
Medical Care (25.6)	17,482	16,742	23,639	6,897
Operation and maintenance of equipment (25.7)	97,280	93,164	131,540	38,377
Subtotal, Other Contractual Services	**1,241,276**	**1,188,750**	**1,678,429**	**489,679**
Supplies and Materials:				
Supplies and materials (26.0)	2,273	2,177	3,073	897
Equipment (31.0)	4,919	4,711	6,651	1,941
Land and Structures (32.0)	965	925	1,305	381
Grants, subsidies, and contributions (41.0)	88,412	84,670	119,548	34,878
Insurance claims and indemnities (42.0)	---	---	---	---
Interest and dividends , Refunds (43.0, 44.0)	53,767	51,492	72,703	21,211
Receivables-collected (61.7)	---	---	---	---
Confidential expenditures (91.0)	19	18	25	7
Subtotal, Supplies and Materials	**150,355**	**143,992**	**203,307**	**59,315**
Total Contractual Services and Supplies	**1,480,462**	**1,412,816**	**1,971,552**	**558,736**
Total User Fees by Object Class	**3,352,144**	**3,491,516**	**3,661,098**	**169,582**
Total User Fees by Object Class, Less Refunds (44.0)	**3,298,377**	**3,440,024**	**3,588,395**	**148,371**

Figure 49 – User Fees by Object Class

PROGRAM LEVEL BY OBJECT CLASS

Food and Drug Administration
Total Program Level by Object Class
(Dollars in Thousands)

(Dollars in Thousands)	FY 2024 Final Post-Reorg	FY 2025 Enacted	FY 2026 President's Budget	FY 2026 PB ± FY 2025 Enacted
Personnel Compensation and Benefits:				
Personnel Compensation:				
Full-time permanent (11.1)	2,335,396	2,487,281	2,014,890	-472,391
Other than full-time permanent (11.3)	197,688	211,600	171,263	-40,337
Other personnel compensation (11.5)	121,092	129,900	105,097	-24,803
Military Personnel - Basic Allowance for Housing (11.6)	101	101	101	---
Military personnel (11.7)	163,858	167,306	167,306	---
Special personnel services payments (11.8)	1,413	1,471	1,196	-275
Subtotal, Personnel Compensation	**2,819,548**	**2,997,659**	**2,459,854**	**-537,805**
Benefits:				
Civilian benefits (12.1)	955,918	1,017,834	824,560	-193,274
Military benefits (12.2)	19,294	19,765	19,765	---
Benefits to former personnel (13.0)	24	24	20	-4
Subtotal, Benefits	**975,236**	**1,037,623**	**844,345**	**-193,278**
Total Personnel Compensation and Benefits	**3,794,784**	**4,035,282**	**3,304,199**	**-731,083**
Contractual Services and Supplies				
Contractual Services:				
Travel and transportation of persons (21.0)	67,803	65,847	73,275	7,428
Transportation of things (22.0)	5,510	5,354	5,901	547
Rental payments to GSA (23.1)	228,038	220,288	190,507	-29,781
Rent payments to others (23.2)	493	479	530	51
Communication, utilities, and misc. charges (23.3)	12,245	11,967	11,713	-254
Printing and reproduction (24.0)	685	669	669	1
Subtotal, Contractual Services	**314,773**	**304,603**	**282,595**	**-22,008**
Other Contractual Services:				
Consulting services (25.1)	243,613	234,580	303,707	69,128
Other services (25.2)	694,362	670,875	820,072	149,196
Purchase of goods and svcs from Govt Acts. (25.3)	1,041,059	1,007,334	1,199,531	192,197
Operation and maintenance of facilities (25.4)	107,030	104,502	104,414	-87
Research and Development Contracts (25.5)	42,459	41,062	49,352	8,289
Medical care (25.6)	38,044	36,843	43,212	6,370
Operation and maintenance of equipment (25.7)	185,845	179,740	215,846	36,107
Subtotal, Other Contractual Services	**2,352,412**	**2,274,936**	**2,736,135**	**461,199**
Supplies and Materials:				
Supplies and materials (26.0)	46,320	45,234	45,002	-232
Equipment (31.0)	32,769	31,936	33,163	1,227
Land and Structures (32.0)	36,290	35,456	34,932	-525
Grants, subsidies, and contributions (41.0)	297,417	288,983	318,504	29,521
Insurance claims and indemnities (42.0)	565	552	537	-14
Interest and dividends , Refunds (43.0, 44.0)	53,767	51,492	72,703	21,211
Receivables-collected (61.7)	---	---	---	---
Confidential expenditures (91.0)	197	192	195	3
Subtotal, Supplies and Materials	**467,325**	**453,845**	**505,035**	**51,190**
Total Contractual Services and Supplies	**3,134,510**	**3,033,384**	**3,523,765**	**490,381**
Total Program Level by Object Class	**6,929,294**	**7,068,666**	**6,827,964**	**-240,702**
Total Program Level by Object Class, Less Refunds (44.0)	**6,875,527**	**7,017,174**	**6,755,261**	**-261,913**

Figure 50 – Program Level by Object Class

DETAIL OF FULL-TIME EQUIVALENTS

Food and Drug Administration
Detail of Full-Time Equivalents (FTE)
Program Level

	FY 2024 Actuals			FY 2025 Enacted			FY 2026 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Human Foods Program	1,231	42	1,273	1,945	42	1,987	1,793	42	1,835
Center for Drug Evaluation and Research	5,679	430	6,109	6,443	430	6,873	5,371	430	5,801
Center for Biologics Evaluation and Research	1,388	49	1,437	1,456	49	1,505	1,197	49	1,246
Center for Veterinary Medicine	734	11	745	772	11	783	603	11	614
Center for Devices and Radiological Health	2,247	54	2,301	2,152	54	2,206	1,737	55	1,792
National Center for Toxicological Research	312	0	312	287	0	287	209	0	209
Center for Tobacco Products	1,209	52	1,261	1,211	52	1,263	905	52	957
Headquarters and Office of the Commissioner	936	38	974	1,018	38	1,056	231	39	270
Office of Investigations and Inspections	4,528	306	4,834	3,598	277	3,875	3,506	292	3,798
Field Laboratory Operations	-	-	-	372	29	401	169	14	183
Color Certification	25	-	25	37	-	37	37	-	37
Export Certification	20	2	22	24	2	26	24	2	26
Priority Review Vouchers (PRV) Tropical Disease	25	1	26	-	-	-	-	-	-
Priority Review Vouchers (PRV) Pediatric Disease	74	1	75	10	1	11	10	1	11
Priority Review Vouchers (PRV) Medical Countermeasures	15	0	15	-	-	-	-	-	-
Over the Counter Monograph (OMUFA)	73	3	76	93	3	96	93	3	96
Opiods - No Year	-	-	-	-	-	-	-	-	-
21st Century Cures (BA Only)	84	2	86	185	2	187	-	-	-
Cancer Moonshot (BA Only)	-	-	-	-	-	-	-	-	-
Total	**18,581**	**990**	**19,571**	**19,603**	**990**	**20,593**	**15,885**	**990**	**16,875**

Five Year History of GS/GM Average Grade

Year	Grade
FY 2021	13
FY 2022	13
FY 2023	13
FY 2024	13
FY 2025	13

* FY 2024 Actual FTE figures do not include an estimated 40 reimbursable, 3 FOIA, 12 PEPFAR, 30 HCFAC, and 31 COVID Supplemental.
**FY 2026 FTE levels reflect estimates for October 1, 2025 and may not represent expected FTE levels across FY 2026. These estimates are subject to change.

Figure 51 – Detail of Full-Time Equivalents

DETAIL OF POSITIONS

Food and Drug Administration
Detail of Positions

	FY 2024 Final	FY 2025 Enacted	FY 2026 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	**$215,537**	**$218,770**	**$218,770**
Executive Service (ES)			
Executive Service	28	28	24
Total Executive Service	**28**	**28**	**24**
Total - ES Salary	**$6,098,716**	**$6,190,196**	**$5,243,081**
General Schedule (GS)			
GS-15	808	867	685
GS-14	3,231	3,465	2,737
GS-13	4,631	4,966	3,922
GS-12	1,852	1,987	1,569
GS-11	576	617	488
GS-10	4	4	3
GS-9	319	342	270
GS-8	17	18	14
GS-7	205	220	174
GS-6	21	23	18
GS-5	23	25	19
GS-4	20	22	17
GS-3	8	9	7
GS-2	4	4	3
GS-1	2	2	1
Total General Schedule	**11,721**	**12,570**	**9,928**
Total - GS Salary	**$1,511,383,923**	**$1,645,175,410**	**$1,299,373,926**
Administrative Law Judges (AL)	---	---	---
Scientific/Senior Level (ST/SL)	1	1	1
Senior Biomedical Research Service (RS)	51	51	43
Scientific Staff Fellows (RG) (Title 42)	938	938	795
Distinguished Consultants/Senior Science Managers (RF) (Title 42)	81	81	69
Former Performance Mgmt Recognition System Employees (GM)	---	---	---
Physicians and Dentists - (GP) (Title 38)	233	233	197
Commissioned Corps (CC):			
Commissioned Corps - 08/07/06	257	257	257
Commissioned Corps - Other	733	733	733
Total Commissioned Corps	**990**	**990**	**990**
Administratively Determined (AD) (includes Title 42)[2]	4,115	4,115	3,486
Wage Grade	7	7	6
Consultants[2]	1,577	1,577	1,336
Total FTE (End of Year)[1]	**19,744**	**20,593**	**16,875**
Average ES Level	1	1	1
Average ES Salary	$215,537	$218,770	$218,770
Average GS grade	13	13	13
Average GS Salary	$128,950	$130,884	$130,884
Average GM Salary	$0	$0	$0
Average GP Salary	$225,177	$228,555	$228,555

[1] Does not include 40 reimbursable, 3 FOIA, 12 PEPFAR, 30 HCFAC, and 31 COVID-19 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.

*FY 2026 FTE levels reflect estimates for October 1, 2025 and may not represent expected FTE levels across FY 2026. These estimates are subject to change.

Figure 52 - Detail of Positions

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FDA SPECIFIC ITEMS

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

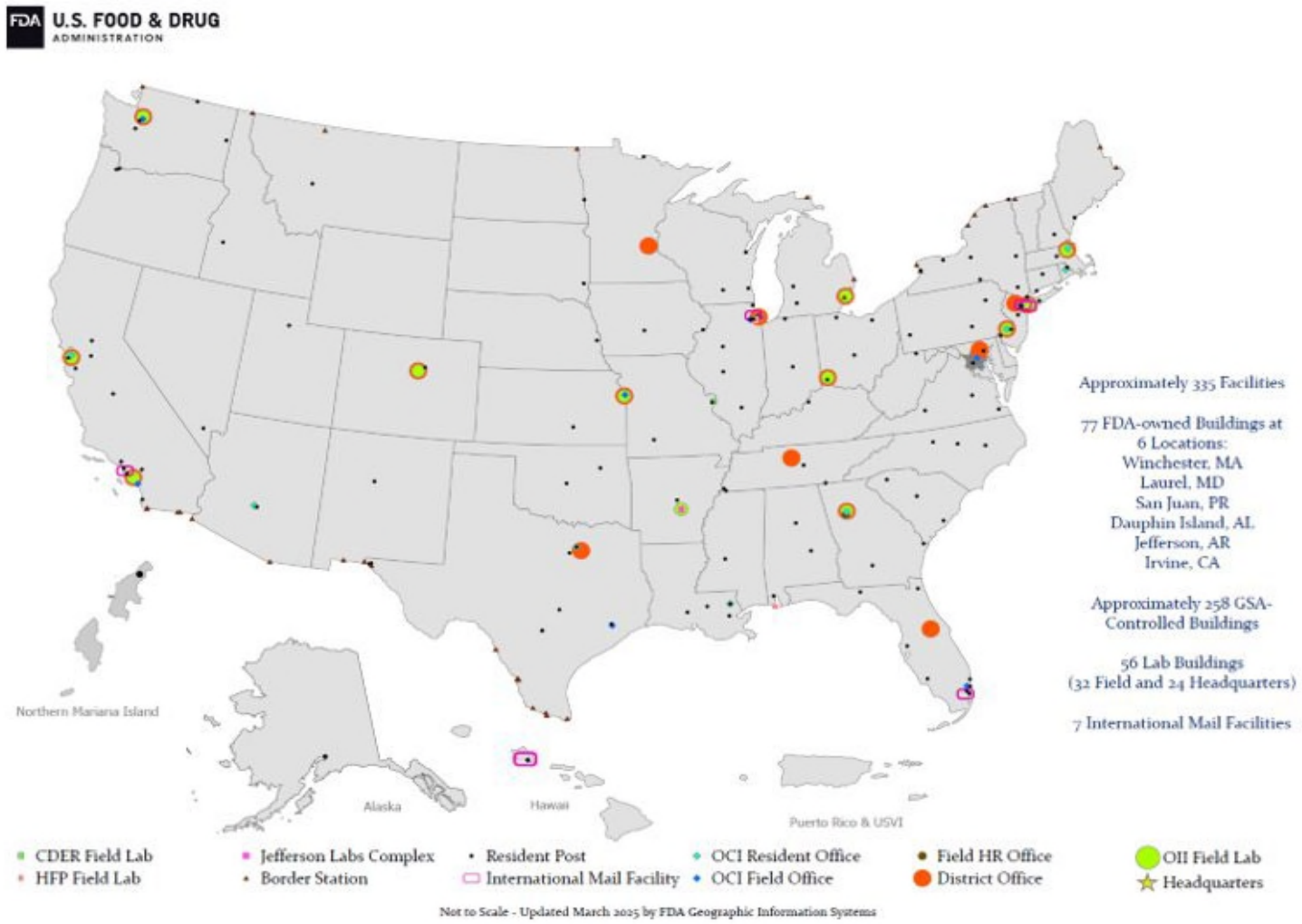

Figure 53 - FDA Facilities Locations

HHS CHARGES AND ASSESSMENTS

FOOD AND DRUG ADMINISTRATION

DHHS Charges and Assessments
FY 2024 Actual, and FY 2025 and 2026 Estimates

Activity	FY 2024 Actual	FY 2025 Estimate	FY 2026 Estimate
Assessments	**$ 601,940**	**$ 647,624**	**$ 647,624**
Fee for Service	**$88,770,300**	**$88,786,990**	**$ 98,103,000**
Program Support Center/OS	$ 25,618,330	$ 26,272,724	$ 29,364,000
Occupational Health Portfolio	$ 1,298,156	$ 1,333,625	$ 1,350,000
Information System Management Service	$ 44,599,841	$ 49,195,789	$ 51,574,000
Office of Human Resource Services	$ 17,348,385	$ 20,059,682	$ 22,135,000
Jointly Funded Services	**$ 4,348,524**	**$ 4,718,894**	**$ 4,486,780**
Total	**$93,720,764**	**$94,153,508**	**$103,237,404**

Figure 54 - HHS Charges and Assessments Summary

Food and Drug Administration
Department of Health and Human Services Charges and Assessments
Fiscal Year 2024 Actuals

	FY24	FY25	FY26
Assessments:	**601,940**	**647,624**	**647,624**
NIH eRA Grants Management System To support migration of FDA Grants Data into the Department's consolidated eRA Grants Management System.	398,749	438,624	438,624
National Telecommunication Information Administration Radio frequency spectrum, a scarce, public resource used by the federal agencies, is essential to U.S. domestic and international communications on a daily basis to provide critical and diverse public services.	10,515	12,000	12,000
Federal Audit Clearinghouse	2,643	5,000	5,000
Credit Monitoring Services OPM shall provide credit monitoring and identity protection to impacted employees.	153,822	155,000	155,000
Federal Interagency Management Councils Support multiple management councils to ensure projects which will drive performance improvement and deliver tangible, measurable impacts.	19,237	20,000	20,000
Federal Government Priority Goals Cross-Agency Priority (CAP) Goals.	16,974	17,000	17,000

Figure 55 - HHS Charges and Assessments Detail 1/5

Fee For Service:	**88,864,712**	**96,861,820**	**104,423,000**
Program Support Center/ Office of the Secretary Provides various services to the FDA, including some Information and Systems Management Services	**25,618,330**	**26,272,724**	**29,364,000**
Financial Management Portfolio	658,782	658,664	638,000
Real Estate, Logistics, and Operations Portfolio Includes Facility Building Operations, Shredding, Storage, Property Disposal, Forms, Property and Travel mgmt., Board of Corrections, Printing, Mail, Storage, HHS Emergency Mgmt., Transportation Policy, Supply Fulfillment, HSPD-12 System Credential & Physical Access, FICAM Services and Identity & Logical Access.	12,790,982	12,583,696	14,166,000
Equal Employment Opportunity Compliance and Operations Includes Complaint Investigations, FAD/Counseling, Mediation, National Final Agency Decision.	2,131,244	1,966,152	2,015,000
Assistance Secretary for Administration Labor and Employee Relations, Office of Operations Mgmt., Office of Program Audit Coordination.	773,417	851,880	861,000
Miscellaneous Services Includes AIM, Acquisition Reform, Category Mgmt., Commissioned Corps Force Mgmt. (CCFM), Departmental Contracts Information System Program (DCIS), Ethics Program, Grants, Broadcast studio, Media Monitoring, OGC Claims, Small Business Consolidation, Strategic Planning, Data PMO, National Security Case Mgmt., Division of Workforce development, Drug Free Workplace, Board of Corrections.	9,263,905	10,212,332	11,684,000
Occupational Health Portfolio FDA Employee Assistance Work/Life Programs, Medical Employability Exams and Reasonable accommodations.	**1,298,156**	**1,333,625**	**1,350,000**
Information & System Management Services	**44,599,841**	**49,195,789**	**51,574,000**
Unified Financial Management Systems (UFMS) Includes services for Consolidated Financial Reporting System (CFRS), Financial Business Intelligence System (FBIS), Financial Systems Control/Program Management and UFMS O&M support.	15,155,150	18,076,591	18,550,000
HCAS Operations and Maintenance HCAS O&M services provide support for daily operations of the HCAS application.	3,101,000	3,316,077	3,460,000
Office of Enterprise Services Government Wide E-Gov Initiatives, IT Vendor Mgmt., Program and Project Mgmt.	2,487,167	2,555,133	2,691,000
Office of Chief Information Officer Application Support, Design & Development, Platform Services, System Integration.	7,045,117	7,421,815	7,406,000
Office of Chief Data Officer Data Strategy and Integration.	1,349,948	1,255,677	2,568,000
Office of Information Security (OIS) Includes HHS Security Enclave and Internet.	7,420,657	7,674,505	7,921,000
Digital Communications	8,040,802	8,895,992	8,978,000
Office of Human Resource Services Includes HR Enterprise Services, HR System Operations, HRIT services, Payroll, Personnel Deployment Division.	**17,348,385**	**20,059,682**	**22,135,000**

Figure 56 - HHS Charges and Assessments Detail 2/5

Jointly Funded Projects	**4,348,524**		**4,718,894**		**4,486,780**
International Health Bilateral Agreement Agreement to provide funding in support of the bilateral-multilateral activities performed on behalf of the Public Service by the Office of Global Health Affairs.	1,581,155		1,475,746		1,475,746
CFO Audit of Financial Statements The audit of the Department's financial statements and the accompanying notes, and a review of its internal controls and compliance with laws and regulations. OIG oversees the contract to an independent audit firm to conduct the HHS financial statement audits and financial management related services.	637,727		670,375		670,375
Advisory Committee for Blood and Tissue Safety and Availability Agreement to provide funding for the advisory committee on Blood Safety.	300,000		62,000		62,000
Office of Regional Health Operations IAG with OS/Office of Public Health & Science to support ten Regional Health Administrators. Their core mission is to promote understanding of and control functions within their respective regions improvements in public health and to conduct specific management.	308,010		261,809		261,809
Intra-department Council on Native American Affairs INCAA is responsible for internal coordination of activities through the Department leading to the development of policies, programs and budgets, and their administration, affecting Native Americans. The Council provides recommendations to the Secretary.	17,000		17,000		17,000
National Science Advisory Board for Biosecurity Agreement with NIH to develop improved biosecurity measures for classes of legitimate biological research that could be misused to threaten public health or national security.	225,000		225,000		-
NIH Negotiation of Indirect Cost Rates Agreement with NIH/OD to support costs associated with the negotiation of indirect cost rates with commercial organizations.	42,826		42,826		42,826
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.	164,182		180,600		180,600
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		125,375		125,375

Figure 57 - HHS Charges and Assessments Detail 3/5

Biosafety and Biosecurity Coordinating Council This will support the administrative management of the Council in efforts to coordinate and collaborate on biosafety and biosecurity issues within HHS.	87,759	87,759	87,759
Implementation of the Digital Accountability and Transparency Act (DATA)	67,692	67,692	67,692
Tick-Borne Disease Working Group The work group will provide expertise and review all efforts within the Department of HHS related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap and to examine research priorities.			
Secretary's Tribal Advisory Committee and Tribal 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	12,000	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.	43,789	43,789	43,789
GAO Audit Activity Augmentation	28,432	34,114	27,000
To support the HHS GAO Portfolio's strategic plan to improve the management and coordination of HHS GAO audit activity across the Department. Ongoing maintenance, licensing agreements, and IT enhancements of the newly developed Information Management Platform for Reporting, Organizing, Vetting and Evaluating platform.			
Dietary Reference Intakes Updates National Academies of Sciences, Engineering and Medicine (NASEM) committee will assess current relevant data and update the Dietary Reference Intakes for energy and provide guidance to the overall macronutrient project.	150,000	150,000	150,000

Figure 58 - HHS Charges and Assessments Detail 4/5

Federalwide Assurance Institutional Review Board Registration Database Modernization To modernize database tools used to fulfill statutory and regulatory responsibilities for the protection of human research subjects.	40,000	-	-
Commission on Asian Americans, Native Hawaiians, and Pacific Islanders Develop, monitor and coordinate executive branch efforts to advance equity, justice and opportunity for AA, NH and PI communities throughout the entire federal government by working in collaboration with the White House.	294,643	64,821	64,821
Development of the Dietary Guidelines for Americans The Dietary Guidelines is required by statute to be published jointly by HHS and the USDA every 5 years.	140,000	1,197,988	1,197,988
Language Access Services Coordination of the Language Access Steering Committee.	33,309	-	-
Healthcare and Public Health Sector Risk Management Agency Program Management The Assistant Secretary for Preparedness and Response (ASPR) coordinates the Sector Risk Management Agency (SRMA) responsibilities on behalf of HHS. Supporting risk mgmt., assessing risk across the sector, conduct day-to-day coordination across federal, state, local, tribal and territorial government and private sector owner-operators, facilitating information sharing related to sector risk and supporting incident management and emergency preparedness efforts.	100,000	-	-
Federal Executive Boards To facilitate communication between Federal agencies to improve coordination of cross agency goals and serve as ambassadors to the local community to promote public service. Through continuity working groups, leadership development training, employee recognition programs, and professional networking opportunities, FEBs assist agencies to accomplish strategic initiatives and mission-related priorities.	74,353	-	-

*Amounts based on requirements funded via FDA Central

Figure 59 - HHS Charges and Assessments Detail 5/5

FDA CENTRAL ACCOUNTS

Food and Drug Administration FDA Central Account						
Program	FY 2024 Actuals		FY 2025 Estimates		FY 2026 Estimates	
(dollars in thousands)	BA	UF	BA	UF	BA	UF
Foods	**21,400**	-	**23,214**	-	**23,214**	-
Center	6,683	-	10,540	-	10,540	-
Field	14,716	-	9,667	-	9,667	-
Field Lab Operations*	-	-	3,007	-	3,007	-
Human Drugs	**15,267**	**41,263**	**14,334**	**41,791**	**14,334**	**41,791**
Center	10,170	38,923	9,756	40,408	9,756	40,408
Field	5,098	2,340	3,349	1,383	3,349	1,383
Field Lab Operations	-	-	1,228	-	1,228	-
Biologics	**5,659**	**7,417**	**5,181**	**8,046**	**5,181**	**8,046**
Center	4,388	7,382	4,338	7,994	4,338	7,994
Field	1,270	35	834	52	834	52
Field Lab Operations	-	-	08	-	08	-
Animal Drugs and Feeds	**4,179**	**1,674**	**4,577**	**1,430**	**4,577**	**1,430**
Center	2,430	1,674	3,192	1,430	3,192	1,430
Field	1,749	-	1,149	-	1,149	-
Field Lab Operations	-	-	236	-	236	-
Devices and Radiological Health	**10,125**	**9,759**	**10,359**	**10,500**	**10,359**	**10,500**
Center	7,424	9,557	8,296	10,366	8,296	10,366
Field	2,700	202	1,774	134	1,774	134
Field Lab Operations	-	-	289	-	289	-
National Center for Toxicological Research	**1,585**	**-**	**1,855**	**-**	**1,855**	**-**
Family Smoking Prevention and Tobacco Control Act	**-**	**10,063**	**-**	**9,846**	**-**	**9,846**
Center	-	9,672	-	9,410	-	9,410
Field	-	391	-	209	-	209
Field Lab Operations	-		-	227	-	227
FDA Headquarters	**6,321**	**4,507**	**4,413**	**5,435**	**4,413**	**5,435**
Total	**64,536**	**74,683**	**63,931**	**77,048**	**63,931**	**77,048**

*Field Lab Operations was created under the reorganization dated 1 Oct 2025, no FY 2024 actuals data available

Figure 60 – FDA Central Accounts

WORKING CAPITAL FUND

The FDA operates a Working Capital Fund (WCF) that enhances visibility into budgetary and management decisions for these services. As an intra-governmental revolving fund, the WCF enables FDA to function in a more efficient business environment by relying on the collection of funds through customer billings. The fund supports FDA in achieving the following objectives:

- Enhance budget justifications and user fee negotiations by providing additional cost information for centrally administered services.
- Streamline budget decisions through an integrated governance and financial infrastructure.
- Establish a customer-focused, service-oriented mechanism by improving customer investment and management decisions.

STRUCTURE

Program Management

To directly support the operation of the WCF, the FDA has established a dedicated WCF Program Management team. This team is responsible for managing and executing the fund's operations, including communications, financial and performance reporting, policy and documentation management, and change management activities. The team operates within the Office of Finance, Budget, and Acquisitions (OFBA), which is part of the Office of Operations.

Governance

The FDA Working Capital Fund Council (WCFC) serves as the primary steering committee for the WCF Program and acts as the decision-making body for matters such as budget, cost recovery, and policy direction. The WCFC includes:

- FDA's Chief Operating Officer (COO)
- Center Directors (customers)
- Business Managers (shared service providers)

A Working Group, composed of deputy executive officers from each of the FDA's Centers, supports the WCFC by reviewing program operations and providing recommendations. The Working Group also includes representatives from service providers, customers, and the OFBA. This group evaluates service catalogs, consumption metrics, and proposed budgets for the annual Cost Allocation assessments associated with the WCF.

Roles and Responsibilities

The roles and responsibilities of the WCFC and its supporting Working Group include:

- Providing direction and oversight for the activities and policies of the WCF.
- Reviewing and determining which activities and services are to be included or excluded in the WCF.
- Coordinating with councils to review and approve cost allocation frameworks, service rates, efficiency and performance targets, and parameters to manage risk.

PROGRAM DESCRIPTION

The WCF provides funding for a wide range of centrally administered shared services across FDA's programs. These services are managed by Offices within the FDA's Office of Operations and FDA Super Offices. Each service falls under specific categories, described in greater detail in this section. Services were identified as ideal candidates for inclusion in the WCF based on the following criteria:

- The services are centrally managed and provided to internal customers across the FDA, making them suitable for a charge-back structure.
- Data regarding consumption-based activities and services, along with appropriate cost data, is available to assess and approximate the full costs to the FDA.
- The services are provided at the Agency level, reducing, or eliminating redundancy and achieving economies of scale.

Information Technology

The WCF also supports Information Technology (IT) services provided by the Office of Digital Transformation (ODT). FDA customers with information, communication, knowledge infrastructure and quality customer service delivery to enhance and sustain systems and IT operations. These services support:

- Personal and mobile computing
- Enterprise applications
- Professional IT services
- Related training and support resources

Informatics and technology-based innovation needs are addressed through the study, development, and testing of prototypes to make recommendations addressing:

- Key mission activities related to big data and analytics
- Cloud and high-performance scientific computing
- Mobility
- Digitization
- Open data

IT support further ensures the appropriate security controls are applied to FDA systems to protect privacy and ensuring confidentiality, integrity, and availability of FDA information in accordance with federal, Department and Agency regulations. The IT function manages technology strategies to reduce costs through the elimination of duplication efforts and adopting new technology to improve services, and leverage knowledge and resources to reduce security and system failures.

Human Resources

Human Resources (HR) services support FDA's workforce through the provision of labor support services. These support services include:

- Benefits and retirement
- Workers' 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
- Implementation of all FDA policies and procedures governing acquisitions
- Interagency 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
- Ethics and integrity assistance to help current and former employees avoid conflicts of interest and follow laws and regulations in their business activities

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