



**DEPARTMENT
of HEALTH
and HUMAN
SERVICES**

Fiscal Year

2027

Food and Drug Administration

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LETTER FROM THE COMMISSIONER



I am proud to present the U.S. Food and Drug Administration's (FDA) congressional justification for the fiscal year (FY) 2027 budget. The FY 2027 budget request of \$7.2 billion is essential to supporting FDA's public health mission. FDA will use this funding to meet its operational imperatives, Make America Healthy Again, and increase the agency's global competitiveness and inspection capabilities.

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, the FDA protects the lives of every American through its numerous public health activities. I am keenly invested in making sure the FDA has all necessary resources to meet its operational imperatives and support its evolution into a user-friendly, common sense driven agency. FDA is in the process of transitioning from a reactionary system to a proactive system and creating new pathways to usher new products to market with transformational potential to Americans' health.

FDA is accelerating the review of products with the potential to address key national priorities. Under the Commissioner's National Priority Voucher pilot program, companies that have agreed to increase affordability, manufacture domestically to promote national security, or address an unmet public health need will receive a regulatory decision within months, dramatically reducing the typical review timeline. In 2025, 18 products received vouchers.

FDA is supporting the department-wide Make America Healthy Again (MAHA) by ensuring the safety of our food and medical products. MAHA is transforming 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 year of the MAHA initiative, FDA has 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. Following the comprehensive review of scientific literature, an expert panel in July 2025, and a public comment period, FDA initiated the removal of “black box” warnings from hormone replacement therapy products for menopause.

FDA will rebuild public trust through promoting radical transparency. We will maintain the integrity of the scientific process by protecting expert recommendations from inappropriate outside influence and increase transparency regarding existing data.

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

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 2027 BUDGET REQUEST

(Dollars in Millions)	FY 2026 Enacted	FY 2027 President's Budget	+/- FY 2026 Enacted
Total Budget Authority Post Transfer /1	3,353.892	3,306.062	(47.830)
Total User Fees	3,641.328	3,921.404	280.076
Total Program Level	6,995.220	7,227.466	232.246
National Center for Toxicological Research (BA)	71.758	-	(71.758)
Total Program Level (including NCTR)	7,066.978	7,227.466	160.488

1/ FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2026 Budget is displayed comparably and as a result does not include \$71.758M for this program.

Figure 1 - Budget Overview

Americans depend on the FDA to effectively manage its vast array of responsibilities to keep the nation's food and drugs safe. FDA's FY 2027 Budget proposes targeted investments to protect public health through the following priorities:

- Ensure FDA meets its operational imperatives
- Support the Make America Healthy Again agenda
- Strengthen America's global competitiveness

FDA's proposed FY 2027 Budget is a total of \$7.2 billion, an overall increase of 3.3 percent above the FY 2026 Enacted level. This includes \$3.3 billion in budget authority, a decrease of 1.4 percent or \$47.8 million below the FY 2026 Enacted level. It also includes \$3.92 billion in user fees, an increase of 7.7 percent or \$280.1 million above the FY 2026 Enacted level. These requests will help FDA address its most urgent public health priorities, Make America Healthy Again, and increase America's global competitiveness.

FY 2027 BUDGET – HIGHLIGHTS

(Dollars in Millions)	FY 2026	FY 2027	
	Enacted	President's Budget	+/- FY 2026 Enacted
Budget Authority /1	3,353.892	3,306.062	(47.830)
Program Level	6,995.220	7,227.466	232.246
Operational Imperatives /2	346.812	389.809	101.533
Protect User Fee Agreements	-	41.600	41.600
Infrastructure /2	346.812	348.209	59.933
<i>White Oak Campus (non-add)</i>	<i>41.998</i>	<i>41.998</i>	-
<i>Other Rent and Rent Related (non-add)</i>	<i>154.879</i>	<i>154.848</i>	-
<i>GSA Rental Payments (non-add)</i>	<i>144.935</i>	<i>146.363</i>	-
<i>Buildings and Facilities (non-add)</i>	<i>5.000</i>	<i>5.000</i>	-
MAHA	34.246	91.246	57.000
Global Competitiveness and Inspection Capability	117.786	156.256	38.470
Reduction of the Federal Bureaucracy	-	(244.833)	(244.833)
1/ FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2026 Budget is displayed comparably and as a result does not include \$71.758M for this program. 2/ Increases for Operational Imperatives, specifically Infrastructure activities, are offset by Reductions of the Federal Bureaucracy.			

Figure 2 - Executive Summary Table

FDA’s FY 2027 Budget contains initiative requests to ensure the agency can continue its mission protecting the public health and address ambitious Administration priorities.

Operational Imperatives

Protecting User Fee Agreements: This \$41.6 million request ensures programs spend the minimum level of non-user fee appropriated budget authority to obligate user fee revenues. With these funds, FDA will streamline applications and support functions, enable more timely approvals, and allow the agency to deliver faster, more accountable, and cost-effective regulatory services. Failure to meet established thresholds would delay and restrict critical FDA program activities.

Infrastructure: The FY 2027 Budget provides \$348.2 million in budget authority for the agency’s infrastructure obligations, including \$59.9 million for GSA Rent and Other Rent and Rent Related costs described below

GSA Rent: Provides \$13.5 million to support space optimization and rent changes associated with continuing occupancies resetting to market rates and for periods of double rent during laboratory decommissioning projects.

Other Rent and Rent Related (OR&RR): Provides \$46.4 million to retain buildings originally planned for elimination in FY 2026.

This funding is necessary to ensure FDA fulfills its facilities obligations while keeping its public health programs fully operational. FDA needs to continue paying the leases and maintenance costs on facilities it retained through FY 2026. FDA must also pay for periods of double rent during laboratory decommissioning projects. Other Rent and Rent Related covers essential costs such as essential maintenance, services, and repairs for FDA facilities. This funding addresses rising operations and maintenance costs due to failing equipment, outdated systems, and escalating security costs.

Make America Healthy Again Initiatives

FDA's FY 2027 Budget includes \$57.0 million in funding to remove unsafe chemicals in our food supply, support artificial intelligence and machine learning initiatives, and invest in research and development for alternatives to animal testing for regulatory science purposes. FDA needs these resources to strengthen existing activities and support new initiatives to keep FDA-regulated foods safe and nutritious. FDA must restore trust in our nation's food system, prioritize public health, and strengthen national nutritional and food safety. The agency's efforts will protect our children's health and directly align with MAHA priorities that will combat the childhood chronic disease crisis and help ensure that Americans live healthier, longer lives.

Global Competitiveness and Inspection Capability

FDA's FY 2027 Budget includes \$38.5 million to support a variety of initiatives to strengthen the agency's efforts to protect patients and consumers while supporting innovation. FDA is in the process of transitioning its routine domestic food safety inspections to states and establishing an integrated framework that focuses FDA expertise on high-risk, complex, or emerging public health issues both domestically and abroad. At the same time, FDA intends to improve its existing capabilities to meet ever-growing inspectional demands. To support this work, FDA's foreign offices require additional resources to expand the agency's global footprint. Within this initiative, FDA will fund efforts to accelerate the establishment of new or advanced pharmaceutical manufacturing facilities in the United States, which will strengthen our supply chains and reduce our dependence on foreign pharmaceutical manufacturing.

Reductions to the Federal Bureaucracy

Additionally, FDA is working towards implementing Simple Reform. This change aligns with FDA's operating model and enables programs to pivot more efficiently to address critical public health needs.

Additional information on this request may be found within the various Program chapters on pages 28 (Human Foods Program), 34 (Human Drugs Program), 41 (Biologics Program), 47 (Animal Drugs and Foods Program), 52 (Devices Program), 58 (Tobacco Program), 63 (Office of the Commissioner), 68 (Infrastructure), and 72 (Buildings and Facilities),

BUDGET EXHIBITS

All Purpose Table

Food and Drug Administration								
FY 2027 All Purpose Table								
(Dollars in thousands)								
(Dollars in Thousands)	FY 2025		FY 2026		FY 2027			
	Final		Enacted		President's Budget		+/- FY 2026 Enacted	
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Human Foods	4,024	1,192,004	3,999	1,184,725	4,049	1,293,226	50	108,501
Budget Authority	3,980	1,179,319	3,956	1,171,319	4,006	1,279,788	50	108,469
User Fees	44	12,685	43	13,406	43	13,438	---	32
<i>Food and Feed Recall</i>	5	1,450	5	1,532	5	1,536	---	4
<i>Food Reinspection</i>	19	5,338	18	5,642	18	5,655	---	13
<i>Voluntary Qualified Importer Program</i>	19	5,324	18	5,627	18	5,640	---	13
<i>Third Party Auditor Program</i>	1	573	2	605	2	607	---	2
Human Drugs	8,057	2,428,505	6,929	2,497,984	6,952	2,537,182	23	39,198
Budget Authority	2,245	724,168	2,002	684,841	2,025	631,818	23	-53,023
User Fees	5,812	1,704,337	4,927	1,813,143	4,927	1,905,364	---	92,221
<i>Prescription Drug (PDUFA)</i>	3,418	1,060,761	2,854	1,132,618	2,854	1,187,414	---	54,796
<i>Generic Drug (GDUFA)</i>	2,270	590,853	1,984	624,708	1,984	656,121	---	31,413
<i>Biosimilars (BsUFA)</i>	120	51,570	85	54,599	85	60,608	---	6,009
<i>Outsourcing Facility</i>	4	1,153	4	1,218	4	1,221	---	3
Biologics	1,730	607,060	1,549	601,291	1,556	574,096	7	-27,195
Budget Authority	827	268,197	774	259,295	781	206,985	7	-52,310
User Fees	903	338,863	775	341,996	775	367,111	---	25,115
<i>Prescription Drug (PDUFA)</i>	828	315,130	711	318,693	711	342,810	---	24,117
<i>Medical Device (MDUFA)</i>	68	21,888	59	22,831	59	23,798	---	967
<i>Generic Drug (GDUFA)</i>	4	1,131	3	341	3	355	---	14
<i>Biosimilars (BsUFA)</i>	3	714	2	131	2	148	---	17
Animal Drugs and Foods	1,044	281,727	963	279,317	985	266,168	22	-13,149
Budget Authority	829	228,708	785	218,399	807	203,219	22	-15,180
User Fees	215	53,019	178	60,918	178	62,949	---	2,031
<i>Animal Drug (ADUFA)</i>	123	26,575	104	33,691	104	33,927	---	236
<i>Animal Generic Drug (AGDUFA)</i>	89	25,372	72	26,095	72	27,886	---	1,791
<i>Food Reinspection</i>	3	942	2	995	2	998	---	3
<i>Third Party Auditor Program</i>	---	130	---	137	---	138	---	1
Devices and Radiological Health	2,680	841,316	2,323	913,719	2,330	1,005,222	7	91,503
Budget Authority	1,520	446,660	1,344	454,874	1,351	465,974	7	11,100
User Fees	1,160	394,656	979	458,845	979	539,248	---	80,403
<i>Prescription Drug (PDUFA)</i>	17	5,567	14	4,592	14	4,786	---	194
<i>Medical Device (MDUFA)</i>	1,105	369,433	933	434,597	933	514,806	---	80,209
<i>Mammography Quality Standards Act (MQSA)</i>	38	19,656	32	19,656	32	19,656	---	---
National Center for Toxicological Research (BA Only)	---	---	---	---	---	---	---	---
Tobacco	1,358	688,827	1,124	688,038	1,124	687,120	---	-918
<i>Family Smoking Prevention and Tobacco Control Act</i>	1,358	688,827	1,124	688,038	1,124	687,120	---	-918

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

Food and Drug Administration								
FY 2027 All Purpose Table								
<i>(Dollars in thousands)</i>								
(Dollars in Thousands)	FY 2025		FY 2026		FY 2027			
	Final		Enacted		President's Budget		+/- FY 2026 Enacted	
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Office of the Commissioner	1,056	364,043	1,000	345,073	1,008	302,900	8	-42,173
<i>Budget Authority</i>	613	234,981	604	219,852	612	171,569	8	-48,283
<i>User Fees</i>	443	129,062	396	125,221	396	131,331	---	6,110
<i>Prescription Drug (PDUFA)</i>	242	65,627	215	64,989	215	67,994	---	3,005
<i>Medical Device (MDUFA)</i>	37	11,953	33	12,413	33	12,903	---	490
<i>Generic Drug (GDUFA)</i>	89	36,642	79	34,147	79	35,747	---	1,600
<i>Biosimilars (BsUFA)</i>	9	793	8	811	8	900	---	89
<i>Animal Drug (ADUFA)</i>	5	722	4	931	4	934	---	3
<i>Animal Generic Drug (AGDUFA)</i>	4	32	3	33	3	36	---	3
<i>Family Smoking Prevention and Tobacco Control Act</i>	53	11,662	50	10,178	50	11,096	---	918
<i>Mammography Quality Standards Act (MQSA)</i>	---	102	---	102	---	102	---	---
<i>Food and Feed Recall</i>	---	88	---	93	---	94	---	1
<i>Food Reinspection</i>	2	559	2	591	2	592	---	1
<i>Voluntary Qualified Importer Program</i>	1	323	1	342	1	342	---	---
<i>Third Party Auditor Program</i>	---	45	---	48	---	47	---	-1
<i>Outsourcing Facility</i>	1	514	1	543	1	544	---	1
<i>Innovative Food Products (Proposed)</i>	---	---	---	---	---	---	---	---
FDA White Oak Campus	---	54,917	---	44,400	---	44,400	---	---
<i>Budget Authority</i>	---	52,498	---	41,998	---	41,998	---	---
<i>User Fees</i>	---	2,419	---	2,402	---	2,402	---	---
<i>Prescription Drug (PDUFA)</i>	---	---	---	---	---	---	---	---
<i>Medical Device (MDUFA)</i>	---	---	---	---	---	---	---	---
<i>Generic Drug (GDUFA)</i>	---	---	---	---	---	---	---	---
<i>Biosimilars (BsUFA)</i>	---	---	---	---	---	---	---	---
<i>Animal Drug (ADUFA)</i>	---	---	---	---	---	---	---	---
<i>Animal Generic Drug (AGDUFA)</i>	---	---	---	---	---	---	---	---
<i>Family Smoking Prevention and Tobacco Control Act</i>	---	2,419	---	2,402	---	2,402	---	---
Other Rent and Rent Related	---	160,259	---	161,366	---	161,326	---	-40
<i>Budget Authority</i>	---	154,879	---	154,879	---	154,848	---	-31
<i>User Fees</i>	---	5,380	---	6,487	---	6,478	---	-9
<i>Prescription Drug (PDUFA)</i>	---	---	---	---	---	---	---	---
<i>Medical Device (MDUFA)</i>	---	---	---	---	---	---	---	---
<i>Generic Drug (GDUFA)</i>	---	---	---	---	---	---	---	---
<i>Biosimilars (BsUFA)</i>	---	---	---	---	---	---	---	---
<i>Animal Drug (ADUFA)</i>	---	559	---	681	---	659	---	-22
<i>Animal Generic Drug (AGDUFA)</i>	---	237	---	234	---	244	---	10
<i>Family Smoking Prevention and Tobacco Control Act</i>	---	4,028	---	4,986	---	4,986	---	---
<i>Food and Feed Recall</i>	---	51	---	54	---	54	---	---
<i>Food Reinspection</i>	---	237	---	250	---	251	---	1
<i>Voluntary Qualified Importer Program</i>	---	199	---	210	---	211	---	1
<i>Third Party Auditor Program</i>	---	29	---	30	---	31	---	1
<i>Outsourcing Facility</i>	---	40	---	42	---	42	---	---
GSA Rental Payments	---	212,288	---	209,023	---	212,937	---	3,914
<i>Budget Authority</i>	---	155,000	---	144,935	---	146,363	---	1,428
<i>User Fees</i>	---	57,288	---	64,088	---	66,574	---	2,486
<i>Prescription Drug (PDUFA)</i>	---	31,884	---	35,147	---	36,638	---	1,491
<i>Medical Device (MDUFA)</i>	---	7,718	---	8,325	---	8,744	---	419
<i>Generic Drug (GDUFA)</i>	---	10,404	---	11,704	---	12,209	---	505
<i>Biosimilars (BsUFA)</i>	---	270	---	300	---	329	---	29
<i>Animal Drug (ADUFA)</i>	---	652	---	849	---	854	---	5
<i>Animal Generic Drug (AGDUFA)</i>	---	343	---	362	---	393	---	31
<i>Family Smoking Prevention and Tobacco Control Act</i>	---	5,064	---	6,396	---	6,396	---	---
<i>Food and Feed Recall</i>	---	86	---	90	---	92	---	2
<i>Food Reinspection</i>	---	406	---	429	---	430	---	1
<i>Voluntary Qualified Importer Program</i>	---	338	---	357	---	358	---	1
<i>Third Party Auditor Program</i>	---	55	---	58	---	59	---	1
<i>Outsourcing Facility</i>	---	68	---	71	---	72	---	1

Figure 4 - All-Purpose Table (2/3)

Food and Drug Administration								
FY 2027 All Purpose Table								
(Dollars in thousands)								
(Dollars in Thousands)	FY 2025		FY 2026		FY 2027			
	Final		Enacted		President's Budget		+/- FY 2026 Enacted	
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Color Certification.....	37	11,109	37	11,109	37	11,109	---	---
Export Certification.....	26	5,185	26	5,185	26	5,185	---	---
Export Certification (Proposed).....	---	---	---	---	---	---	---	---
Foreign Food Facility and Registration Fee (Proposed).....	---	---	---	---	---	71,000	---	71,000
Third Party Auditor Program (Proposed).....	---	---	---	---	---	---	---	---
FSMA Reinspection and Recall Fees (Proposed).....	---	---	---	---	---	---	---	---
Priority Review Vouchers (PRV) Tropical Disease.....	---	2,867	---	3,030	---	3,037	---	7
Priority Review Vouchers (PRV) Pediatric Disease.....	11	8,969	11	9,479	11	9,501	---	22
Priority Review Vouchers (PRV) Medical Countermeasures.....	---	---	---	---	---	---	---	---
Over the Counter Monograph.....	96	36,467	96	37,981	96	39,557	---	1,576
Food and Drug Safety – No Year (P.L. 113-6).....	---	---	---	---	---	---	---	---
Food Safety.....	---	---	---	---	---	---	---	---
Drug Safety.....	---	---	---	---	---	---	---	---
21st Century Cures (BA Only).....	187	50,000	---	---	---	---	---	---
Foreign Inspection Pilot - No Year.....	---	---	---	---	---	---	---	---
Opioids - No Year.....	---	---	---	---	---	---	---	---
Subtotal, Salaries and Expenses.....	20,306	6,945,543	18,057	6,991,720	18,174	7,223,966	117	232,246
Buildings and Facilities (Budget Authority).....	---	5,000	---	5,000	---	5,000	---	---
Total Program Level.....	20,306	6,950,543	18,057	6,996,720	18,174	7,228,966	117	232,246
User Fees:								
Current Law								
Prescription Drug (PDUFA).....	4,505	1,478,969	3,794	1,556,039	3,794	1,639,642	---	83,603
Medical Device (MDUFA).....	1,210	410,992	1,025	478,166	1,025	560,251	---	82,085
Generic Drug (GDUFA).....	2,363	639,030	2,066	670,900	2,066	704,432	---	33,532
Biosimilars (BsUFA).....	132	53,347	95	55,841	95	61,985	---	6,144
Animal Drug (ADUFA).....	128	28,508	108	36,152	108	36,374	---	222
Animal Generic Drug (AGDUFA).....	93	25,984	75	26,724	75	28,559	---	1,835
Family Smoking Prevention and Tobacco Control Act.....	1,411	712,000	1,174	712,000	1,174	712,000	---	---
Subtotal, Current Law.....	9,842	3,348,830	8,337	3,535,822	8,337	3,743,243	---	207,421
Indefinite								
Mammography Quality Standards Act (MQSA).....	38	19,758	32	19,758	32	19,758	---	---
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.....	---	2,867	---	3,030	---	3,037	---	7
Priority Review Vouchers (PRV) Pediatric Disease.....	11	8,969	11	9,479	11	9,501	---	22
Priority Review Vouchers (PRV) Medical Countermeasures.....	---	---	---	---	---	---	---	---
Food and Feed Recall.....	5	1,675	5	1,769	5	1,776	---	7
Food Reinspection.....	24	7,482	22	7,907	22	7,926	---	19
Voluntary Qualified Importer Program.....	20	6,184	19	6,536	19	6,551	---	15
Third Party Auditor Program.....	1	832	2	878	2	882	---	4
Outsourcing Facility.....	5	1,775	5	1,874	5	1,879	---	5
Over the Counter Monograph.....	96	36,467	96	37,981	96	39,557	---	1,576
Subtotal, Indefinite.....	263	102,303	255	105,506	255	107,161	---	1,655
Proposed								
Foreign Food Facility and Registration Fee (Proposed).....	---	---	---	---	---	71,000	---	71,000
Subtotal, Proposed.....	---	---	---	---	---	71,000	---	71,000
Total User Fees.....	10,105	3,451,133	8,592	3,641,328	8,592	3,921,404	---	280,076
Total Budget Authority, Pre-Transfer.....	10,201	3,499,410	9,465	3,355,392	9,582	3,307,562	117	-47,830
BA, S&E.....	10,014	3,444,410	9,465	3,350,392	9,582	3,302,562	117	-47,830
BA, B&F.....	---	5,000	---	5,000	---	5,000	---	---
21st Century Cures.....	187	50,000	---	---	---	---	---	---
Total Program Level, Pre-Transfer.....	20,306	6,950,543	18,057	6,996,720	18,174	7,228,966	117	232,246
IHHS OIG transfer (BA Only).....	---	-1,500	---	-1,500	---	-1,500	---	---
Total Budget Authority, Post-Transfer.....	10,201	3,497,910	9,465	3,353,892	9,582	3,306,062	117	-47,830
Total User Fees.....	10,105	3,451,133	8,592	3,641,328	8,592	3,921,404	---	280,076
Total Program Level, Post-Transfer.....	20,306	6,949,043	18,057	6,995,220	18,174	7,227,466	117	232,246
Total Program Level, Post-Transfer (including NCTR).....	20,593	7,026,783	18,256	7,066,978	18,174	7,227,466	-82	160,488

* Excludes emergency and supplemental funding and permissive transfers.
 ** FY 2025 Final level includes the FDA-wide reorganization and WCF comparability adjustment. This level also includes a \$7M reprogramming from HFP Center to Field Laboratory Operations and one-time \$8M transfer notification to shift funds from GSA Rent to HFP for the planned move and decommissioning of the Atlanta facility.
 *** FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2025 and FY 2026 Budget is displayed comparably and as a result does not include \$77.740M in FY 2025 and \$71.758M in FY 2026 for this program.
 **** User Fees reflect the 5yr plan estimated target revenue.
 ***** 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 5 - All-Purpose Table (3/3)

BUDGET AUTHORITY CROSSWALK

FY 2027 JUSTIFICATION CROSSWALK

**Food and Drug Administration
FY 2027 Congressional Justification BA Crosswalk**

(Dollars in Thousands)	FY 2026 Enacted		FY 2027 CJ												FY 2027 President's Budget	
			Reduction of the Federal Bureaucracy		Operational Imperatives				MAHA		Global Competitiveness/ Inspection Capability		Total Changes			
					Protect User Fee Agreements		Infrastructure and B&F									
	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000	FTE	\$000
Salaries and Expenses Account:																
Human Foods.....	3,956	1,171,319	—	65,469	—	—	—	—	30	25,000	20	18,000	50	108,469	4,006	1,279,788
Human Drugs.....	2,002	684,841	—	-91,223	—	24,200	—	—	—	—	23	14,000	23	-53,023	2,025	631,818
Biologics.....	774	259,295	—	-54,310	—	—	—	—	—	—	7	2,000	7	-52,310	781	206,985
Animal Drugs and Foods.....	785	218,399	—	-43,480	—	8,300	—	—	22	20,000	—	—	22	-15,180	807	203,219
Devices and Radiological Health.....	1,344	454,874	—	—	—	9,100	—	—	—	—	7	2,000	7	11,100	1,351	465,974
National Center for Toxicological Research.....	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Office of the Commissioner.....	604	219,852	—	-62,753	—	—	—	—	3	12,000	5	2,470	8	-48,283	612	171,569
FDA White Oak Campus.....	—	41,998	—	—	—	—	—	—	—	—	—	—	—	—	—	41,998
Other Rent and Rent Related.....	—	154,879	—	-46,464	—	—	—	46,433	—	—	—	—	—	-31	—	154,848
GSA Rental Payments.....	—	144,935	—	-12,072	—	—	—	13,500	—	—	—	—	—	1,428	—	146,363
Subtotal, Salaries and Expenses Account.....	9,465	3,350,392	—	-244,833	—	41,600	—	59,933	55	57,000	62	38,470	117	-47,830	9,582	3,302,562
Buildings and Facilities Account.....	—	5,000	—	—	—	—	—	—	—	—	—	—	—	—	—	5,000
Total Budget Authority, Pre-Transfer.....	9,465	3,355,392	—	-244,833	—	41,600	—	59,933	55	57,000	62	38,470	117	-47,830	9,582	3,307,562
21st Century Cures	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Total Budget Authority with 21st Century Cures.....	9,465	3,355,392	—	-244,833	—	41,600	—	59,933	55	57,000	62	38,470	117	-47,830	9,582	3,307,562
HHS OIG transfer.....	—	-1,500	—	—	—	—	—	—	—	—	—	—	—	—	—	-1,500
Total Budget Authority, Post-Transfer.....	9,465	3,353,892	—	-244,833	—	41,600	—	59,933	55	57,000	62	38,470	117	-47,830	9,582	3,306,062
Total Budget Authority, Post-Transfer (including NCTR).....	9,664	3,425,650	—	—	—	—	—	—	—	—	—	—	—	-82	9,582	3,306,062

*FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. FY 2026 Budget is displayed comparably and as a result does not include \$71.758M in FY 2026 for this program.

Figure 6 - Budget Authority Crosswalk (1/1)

SUMMARY OF CHANGES

Food and Drug Administration						
Summary of Changes						
<i>(Dollars in millions)</i>						
FY 2026 Enacted/1						
Total estimated budget authority.....						\$3,353.892
(Obligations).....						
FY 2027 President's Budget						
Total estimated budget authority.....						\$3,306.062
(Obligations).....						
Net Change.....						-\$47.830
	FY 2026 Enacted		FY 2027 President's Budget		FY 2027 +/- FY 2026	
	FTE	BA	FTE	BA	FTE	BA
Increases:						
Operational Imperatives.....						
Protect User Fee Agreements.....	--	--	--	\$41.600	--	+\$41.600
Infrastructure (WO, OR&RR, GSA) and B&F/2.....	--	\$346.812	--	\$348.209	--	+\$59.933
MAHA.....						
Remove Chemicals from our Food.....	--	\$34.246	--	\$84.246	--	+\$50.000
AI/ML Activities.....	--	--	--	\$2.000	--	+\$2.000
Alternatives To Animal Testing.....	--	--	--	\$5.000	--	+\$5.000
Global Competitiveness and Inspection Capability						
Domestic Food Safety Inspections.....	--	\$116.000	--	\$125.000	--	+\$9.000
Improving Inspectorate Capability.....	--	--	--	\$9.000	--	+\$9.000
Foreign Office Expansion.....	--	\$1.786	--	\$4.256	--	+\$2.470
Oil Foreign Inspections.....	--	--	--	\$9.000	--	+\$9.000
Accelerate Advanced Pharmaceutical Manufacturing.....	--	--	--	\$9.000	--	+\$9.000
Subtotal, Program Increases.....	--	\$498.844	--	\$637.311	--	+\$197.003
Total Increases.....	--	\$498.844	--	\$637.311	--	+\$197.003
Decreases:						
Reduction of the Federal Bureaucracy.....	--	--	--	-\$244.833	--	-\$244.833
Subtotal, Program Decreases.....	--	--	--	-\$244.833	--	-\$244.833
Total Decreases.....	--	--	--	-\$244.833	--	-\$244.833
Net Change.....	--	\$498.844	--	\$392.478	--	-\$47.830

1/ The FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2026 Budget is displayed comparably and as a result does not include \$71.758M for this program.

2/Increases for Operational Imperatives, specifically Infrastructure activities, are offset by Reductions of the Federal Bureaucracy.

Figure 7 – 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	6,804,535,000	6,927,405,000	6,843,190,000
FY 2026.....	6,642,881,000	6,682,889,000	7,070,244,000	6,957,972,000
FY 2027.....	7,045,805,000			

* Excludes indefinite user fees, proposed user fees, and B&F.

** Excludes funding for 21st Century Cures (FY 2018 – FY 2025).

*** FY 2021 excludes \$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 to the HHS Office of Inspector General.

Figure 8 – Salaries & Expenses Appropriations History

Buildings and Facilities

(dollars)	Budget Estimate to Congress	House Allowance	Senate Allowance	Appropriation
General Fund Appropriation:				
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	1,000,000	5,000,000	5,000,000
FY 2027.....	5,000,000			

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

Figure 9 – Buildings & Facilities Appropriations History

APPROPRIATIONS LANGUAGE AND ANALYSIS

APPROPRIATIONS LANGUAGE

Salaries and Expenses

(Including Transfers of Funds)

For necessary expenses of the Food and Drug Administration, including hire and purchase of passenger motor vehicles; for payment of space rental and related costs pursuant to Public Law 92–313 for programs and activities of the Food and Drug Administration which are included in this Act; for rental of special purpose space in the District of Columbia or elsewhere; for miscellaneous and emergency expenses of enforcement activities, authorized and approved by the Secretary and to be accounted for solely on the Secretary’s certificate, not to exceed \$25,000; and notwithstanding section 521 of Public Law 107–188; [\$6,957,972,000] \$7,045,805,000: Provided, That of the amount provided under this heading, [\$1,556,039,000] \$1,639,642,000 shall be derived from prescription drug user fees authorized by 21 U.S.C. 379h, and shall be credited to this account and remain available until expended; [\$478,166,000] \$560,251,000 shall be derived from medical device user fees authorized by 21 U.S.C. 379j, and shall be credited to this account and remain available until expended; [\$670,900,000] \$704,432,000 shall be derived from human generic drug user fees authorized by 21 U.S.C. 379j–42, and shall be credited to this account and remain available until expended; [\$55,841,000] \$61,985,000 shall be derived from biosimilar biological product user fees authorized by 21 U.S.C. 379j–52, and shall be credited to this account and remain available until expended; [\$36,152,000] \$36,374,000 shall be derived from animal drug user fees authorized by 21 U.S.C. 379j–12, and shall be credited to this account and remain available until expended; [\$26,724,000] \$28,559,000 shall be derived from generic new animal drug user fees authorized by 21 U.S.C. 379j–21, and shall be credited to this account and remain available until expended; \$712,000,000 shall be derived from tobacco product user fees authorized by 21 U.S.C. 387s, and shall be credited to this account and remain available until expended: Provided further, That in addition to and notwithstanding any other provision under this heading, amounts collected for prescription drug user fees, medical device user fees, human generic drug user fees, biosimilar biological product user fees, animal drug user fees, and generic new animal drug user fees that exceed the respective fiscal year [2026] 2027 limitations are appropriated and shall be credited to this account and remain available until expended: Provided further, That fees derived from prescription drug, medical device, human generic drug, biosimilar biological product, animal drug, and generic new animal drug assessments for fiscal year [2026] 2027, including any such fees collected prior to fiscal year [2026] 2027 but credited for fiscal year [2026] 2027, shall be subject to the fiscal year [2026] 2027 limitations: Provided further, That the Secretary may accept payment during fiscal year [2026] 2027 of user fees specified under this heading and authorized for fiscal year [2027] 2028, prior to the due date for such fees, and that amounts of such fees assessed for fiscal year [2027] 2028 for which the Secretary accepts payment in fiscal year [2026] 2027 shall not be included in amounts under this heading: Provided further, That none of these funds shall be used to develop, establish, or operate any program of user fees authorized by 31 U.S.C. 9701: Provided further,

That of the total amount appropriated: (1) [\$1,171,319,000] \$1,279,788,000 shall be for the Human Foods Program and for related field activities, including inspections, investigations, and import operations, conducted by the Human Foods Program, the Office of Inspections and Investigations, or the Office of the Chief Scientist, of which no less than \$15,000,000 shall be used for inspections of foreign seafood manufacturers and field examinations of imported seafood; (2) [\$2,496,766,000] \$2,535,961,000 shall be for the Center for Drug Evaluation and Research and for related field activities, including inspections, investigations, and import operations, conducted by the Center, the Office of Inspections and Investigations, or the Office of the Chief Scientist, of which no less than \$10,000,000 shall be for pilots to increase unannounced foreign inspections and shall remain available until expended; (3) [\$601,291,000] \$574,096,000 shall be for the Center for Biologics Evaluation and Research and for related field activities, including inspections, investigations, and import operations, conducted by the Center, the Office of Inspections and Investigations, or the Office of the Chief Scientist; (4) [\$278,185,000] \$265,032,000 shall be for the Center for Veterinary Medicine and for related field activities, including inspections, investigations, and import operations, conducted by the Center, the Office of Inspections and Investigations, or the Office of the Chief Scientist; (5) [\$894,063,000] \$985,566,000 shall be for the Center for Devices and Radiological Health and for related field activities, including inspections, investigations, and import operations, conducted by the Center, the Office of Inspections and Investigations, or the Office of the Chief Scientist; (6) [\$71,758,000] \$688,038,000 shall be for the National Center for Toxicological Research; (7) \$687,120,000 shall be for the Center for Tobacco Products and for related field activities, including inspections, investigations, and import operations, conducted by the Center, the Office of Inspections and Investigations, or the Office of the Chief Scientist; [(8) \$205,180,000] (7) \$205,137,000 shall be for Rent and Related activities, of which \$44,400,000 is for White Oak Consolidation, other than the amounts paid to the General Services Administration for rent; [(9) \$208,018,000] (8) \$211,926,000 shall be for payments to the General Services Administration for rent; and [(10) \$343,354,000] (9) \$301,179,000 shall be for other activities, including the Office of the Commissioner of Food and Drugs, the Office of the Chief Scientist, the Office of the Chief Medical Officer, and central services for these offices: Provided further, That not to exceed \$25,000 of this amount shall be for official reception and representation expenses, not otherwise provided for, as determined by the Commissioner: Provided further, That any transfer of funds pursuant to, and for the administration of, section 770(n) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379dd(n)) shall only be from amounts made available under this heading for other activities and shall not exceed \$2,000,000: Provided further, That of the amounts that are made available under this heading for “other activities”, and that are not derived from user fees, \$1,500,000 shall be transferred to and merged with the appropriation for “Department of Health and Human Services—Office of Inspector General” for oversight of the programs and operations of the Food and Drug Administration and shall be in addition to funds otherwise made available for oversight of the Food and Drug Administration; Provided further, That funds may be transferred from one specified activity to another with the prior [approval of] *notification to* the Committees on Appropriations of both Houses of Congress.

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

Buildings and Facilities

For plans, construction, repair, improvement, extension, alteration, demolition, and purchase of fixed equipment or facilities of or used by the Food and Drug Administration, where not otherwise provided, \$5,000,000, to remain available until expended.

APPROPRIATION LANGUAGE ANALYSIS

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

Language Provision	Explanation
Collect Foreign Food Facility Registration Fees	Amend section 415 the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish a biennial registration fee for all foreign human and animal food facilities. This would align with current biennial registration renewal requirements and provide vital additional funding to support FDA’s human and animal food programs and the critical work to keep an accurate inventory of food facilities that is integral to protecting public health and ensuring the safety of foods imported into the United States.

LEGISLATIVE PROPOSALS

Holding Firms Accountable Using Misleading Advertising to Drive Profits at the Expense of Consumers

This proposal would update FDA's authorities with respect to direct-to-consumer (DTC) advertising. Specifically, this proposal would deem a drug to be misbranded under section 502 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 352) if a DTC drug advertisement lacks fair balance and creates a misleading impression regarding FDA approval, the scope of the FDA-approved indication(s) and the limitations of use, or the drug's efficacy and benefits, including by making or suggesting overstated representations that are not supported. It would also update the FD&C Act to clarify that a compounded drug is deemed to be misbranded if an advertisement's representation is false or misleading or creates a misleading impression by failing to clearly and prominently disclose that the FDA has not approved or evaluated these products for safety, effectiveness, or quality prior to marketing; representing or suggesting the compounded drugs are safe and effective without any evidence; making misleading comparative claims to a particular FDA-approved drug or class of drugs; misrepresenting the data available about the compounded drug or its active ingredients for particular indications based on clinical trials of FDA-approved drugs containing the same active ingredients; or omitting risk information or otherwise failing to provide fair balance. FDA needs additional authorities to more effectively address DTC advertising that lacks fair balance and is frequently misleading and confusing to consumers and patients.

Strengthening Oversight of Critical and Other Foods to Better Protect Infants and Children

The proposal would strengthen oversight of critical foods, such as infant formula and other foods consumed by infants and young children. This proposal also has applicability to all foods to protect against contaminants in foods. Specifically for infant formula, the proposal would expand section 412(e) of the FD&C Act to strengthen oversight of infant formula by requiring industry to report all product positive test results for relevant pathogens; and expand section 412 of the FD&C Act to explicitly require infant formula manufacturers to conduct robust environmental monitoring to identify the presence of relevant pathogens on surfaces from which the risk of contamination is the greatest and maintain the results of such testing for FDA inspection or remote record review. In addition, this proposal strengthens oversight of contaminants in foods by adding mechanisms for FDA to set binding limits for contaminants in foods, requiring industry to conduct final testing of products for contaminants, and addressing mandatory recall authority for foods containing contaminants at levels above limits established by FDA. These authorities would help FDA ensure the safety of critical foods and better understand levels of contaminants in foods.

Allow Companies Manufacturing Generic Medications Domestically to File Paragraph IV Certifications Earlier, Giving Exclusivity Rights to US Manufacturers

This proposal would amend current law to allow domestic generic drug manufacturers to submit Abbreviated New Drug Applications earlier than foreign manufacturers in certain circumstances, which may help repatriate the U.S. pharmaceutical supply chain by making domestic generic drug manufacturers more likely to be eligible for 180-day exclusivity. The proposal would amend section 505(j)(5)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the Act) to allow generic companies based in the U.S. that currently manufacture a generic drug in the U.S. or are making investments in new domestic manufacturing facilities to substantially increase manufacturing capacity of a generic drug in the U.S., to file their application and paragraph IV certification(s) on the timeline currently codified in section 505(j)(5)(F)(ii) of the Act, and delay by one month when other companies can file their application and paragraph IV certification(s).

Ensure FDA Access to Industry Data to Strengthen Food Chemical Safety

This proposal would strengthen FDA’s post-market surveillance of food chemical safety. A food additive must obtain pre-market authorization from FDA unless it is a substance generally recognized as safe which is excluded from the “food additive” definition under section 201(s) of the FD&C Act or unless it is a prior-sanctioned substance that is excepted from the “food additive” definition under section 201(s)(4) of the FD&C Act). A color additive must also obtain pre-market authorization from FDA. However, in the post-market context, FDA has more limited authority to require industry to provide updated safety information. This authority would require affected industry to provide certain post-market data to FDA and require affected industry to conduct post-market safety evaluations and reassessments of chemicals added to food and to submit the results to FDA. This authority would also (1) specify additional categories of information industry must consider in post-market safety evaluations and reassessments; (2) establish minimum data standards for conducting post-market safety evaluations and reassessments; and (3) establish other conditions, as needed, for conducting post-market safety evaluations and reassessments.

Allow Disclosure of Certain Information in Complete Response Letters

This proposal would enhance FDA’s authority to publicly disclose information on deficiencies in safety and efficacy data provided to a sponsor in complete response letters (CRLs) for original New Drug Applications (NDAs), original Biologics License Applications (BLAs), and NDA and BLA efficacy supplements. FDA’s proposal would amend the Federal Food, Drug, and Cosmetic Act to provide explicit authority to disclose certain information related to FDA’s issuance of the CRL. The disclosure of certain information in CRLs may make drug development more efficient for multiple stakeholders, as it could help others prevent similar deficiencies in their own development programs and marketing applications.

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

Under section 801 of the Federal Food, Drug, and Cosmetics Act, importers of commercial shipments have the option to export an entry refused by FDA within 90 days of the refusal regardless of the seriousness of the public health concern posed by the product. FDA proposes to amend section 801 to give the Agency authority to require an importer to destroy any FDA-regulated product(s) refused entry into the U.S. that presents a significant public health concern, thus removing their option to export such product(s). The Agency has observed importers exporting or attempting to re-import commercial-sized shipments that pose a significant public health concern including food contaminated with Salmonella, Listeria and carcinogenic unapproved animal drugs; human drugs such as hand sanitizer contaminated with methanol; and misbranded or adulterated devices such as contact lenses, COVID-19 test kits, and personal protective equipment. In May 2023, a high-volume importer/wholesaler pled guilty to attempting to re-import 2100 cartons of frozen eels from China that were refused by FDA because testing confirmed contamination with a carcinogenic unapproved animal drug. FDA believes this new authority would prevent re-importation of refused products and would deter importers from seeking to import products they know or have reason to believe would pose a significant public health risk and could be ordered destroyed. This authority would also increase efficiency by reducing the need for Customs and Border Protection to seize unsafe FDA-regulated products and allow the Agency to require importers to pay the storage and destruction costs up front, thereby avoiding additional legal action to recoup such costs.

Create Efficiencies for Review and Approval of Biosimilar Applications and Deem that Approved Biosimilars are Interchangeable

This proposal would streamline the review and approval of biosimilars by amending section 351 of the Public Health Service (PHS) Act to no longer include a separate statutory standard for a determination of interchangeability and deem all approved biosimilars to be interchangeable with their respective reference products. A determination of interchangeability pertains to pharmacy substitution of an interchangeable biosimilar for its reference product without the intervention of the prescribing health care provider. The statutory distinction between biosimilar products and interchangeable biosimilar products has led to confusion and misunderstanding, including among patients and healthcare providers, about the safety and effectiveness of biosimilars and about whether interchangeable biosimilars are safer or more effective than other biosimilars. Both biosimilars and interchangeable biosimilars are just as safe and effective as their respective reference products and can be used in place of their respective reference products. This proposal would make the U.S. biosimilar program more consistent with current scientific understanding, as well as with the approach adopted by other major regulatory jurisdictions such as the European Union that permit interchangeability of biosimilars with their respective reference products upon approval, thus making the US biosimilar market more competitive with our European counterparts and lower costs for consumers.

This proposal would also create a presumption that a comparative clinical study that includes the assessment of efficacy is unnecessary to support a demonstration of biosimilarity upon a

prospective applicant's written request, unless FDA provides a justification within an agreed-upon time period as to why such study is necessary or why additional scientific information is needed for the determination. This would further streamline biosimilar development programs, where scientifically appropriate, and provide additional clarity to prospective applicants about the type(s) of assessments that are necessary to support a determination of biosimilarity for specific biological products.

This proposal would also amend the PHS Act to remove the requirement in section 351(k)(5)(B) that biosimilar applications specifically be reviewed by the review division responsible for the review and approval of the reference product application. This change will increase the efficiency of the review of biosimilar applications by allowing the FDA to concentrate all biosimilar reviews in a single review division that specializes in biosimilar review and licensure.

Increase Agency Flexibility Regarding the Convening of Advisory Committees and the Composition of Such Committees

This proposal would increase the Agency's flexibility to appoint representatives of consumer interests and the drug manufacturing industry to Scientific Advisory Panels only where appropriate as opposed to current law, which requires the Commissioner to appoint such representatives to advisory committees. This statutory change would give the FDA the flexibility to optimize the Advisory Committee program, including updates to Advisory Committee charter documents that outline the types and minimum number of advisory committee meetings annually. This statutory change will also give the Agency the authority to adopt flexible advisory committee policies that uphold the principle of common-sense, gold standard science. Last, as a practical matter, this update will give the Agency the ability to determine if and how frequently advisory committees should meet and whether a specified number of meetings are unduly burdensome.

Strengthen Enforcement Against Importation of Unauthorized Electronic Nicotine Delivery Systems (ENDS) and Other Illegal Tobacco Products

This proposal would amend the FDCA to address significant challenges in addressing the sale and distribution of unauthorized tobacco products across the supply chain, especially at the time of import. While FDA is engaged in ongoing efforts to prevent the importation of unauthorized e-cigarettes, these efforts are complicated by multiple challenges, including intentional circumvention of import controls, including misdeclarations and port-shopping; litigation-related impediments; diminished deterrent impact of current consequences for violations; and lack of material information available to FDA to make decisions about imported products. Additionally, the tobacco program does not have the full scope of enforcement tools that are available for other FDA-regulated products, such as drugs and devices. This proposal would address those challenges by 1) Revising Section 905 (21 U.S.C. 387e) to require annual registration and product listing for importers and wholesale distributors of tobacco products; 2) Revising Section 905(g) (21 U.S.C. 387e(g)) from a biennial inspection requirement to a risk-based inspection

schedule for foreign and domestic registered entities; ; 3) Amending Section 301 (21 U.S.C. 331) to include making a false statement with respect to a tobacco product being offered for import to the list of prohibited acts; and, 4) Revise Section 912(a)(1)(B) of the FD&C Act (21 U.S.C. 3871(a)(1)(B)) to explicitly allow only adversely affected applicants to bring suit. These changes would support a robust, multifaceted framework for tobacco products.

Mutual Recognition Authority for Bioresearch Monitoring Inspection

This proposal would revise FDA's Mutual Recognition Agreement (MRA) authority under section 809 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to include authority, if deemed necessary, for FDA to recognize good clinical practice (GCP) or good laboratory practice (GLP) inspection reports from foreign regulatory counterparts that the Agency finds capable of conducting such inspections. Currently, the section 809 authority for MRAs is limited to certain establishments registered under section 510(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act), which applies to facilities that manufacture, prepare, propagate, compound, or process human and veterinary drugs. MRAs which cover the Agency's bioresearch monitoring program would further solidify FDA's review(s) of innovative and generic medicines, helping bring life-saving therapies and drugs that Americans rely on to market. Further, as part of mutual recognition agreements foreign counterparts can also rely on FDA inspection reports reducing the regulatory burden on American clinical research facilities and institutions, giving FDA maximum resourcing flexibility to focus compliance efforts on facilities posing greater compliance risks.

Collect Foreign Food Facility Registration Fees

This proposal would amend section 415 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) to establish a biennial registration fee for all foreign human and animal food facilities. Current law does not authorize FDA to collect registration fees from foreign facilities that are required to register under section 415 of the FD&C Act (21 U.S.C. 350d). Section 421 of the FD&C Act (21 U.S.C. 350j) sets targets for the number of annual inspections; however, resources required to conduct foreign food facility inspections and oversight activities are significant. FDA relies on registration data, including the location of the facilities, the type of food manufactured, contact information for the facility, and other information to inform foreign inspections and to target import screening. This proposal would align with current registration renewal requirements and provide vital additional funding to support FDA's human and animal food program work abroad, including its food chemical safety program, thus ensuring the safety of foods imported into the United States and delivering on the President's commitment to Making America Healthy Again.

Create an Additional Abbreviated Licensure Pathway for Biological Products

This proposal would amend section 351(a) of the Public Health Service Act (PHS Act) to create an abbreviated licensure pathway for biological products that are intended to differ from an FDA-

approved biological product, but for which scientifically justified reliance on FDA’s previous determination of safety, purity, and potency for a biological product and/or on published literature would enable a more streamlined and efficient development program. The proposed abbreviated licensure pathway would be conceptually similar to the pathway for follow-on drug products in section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, which expressly allows an applicant to rely for approval on investigations that were not conducted by or for the applicant (and for which the applicant has not obtained a right of reference or use). Such an abbreviated licensure pathway would enhance biological product competition and innovation and enable more streamlined and efficient development programs while maintaining robust safety, purity, and potency standards.

Explicitly Address Generic Drug-Device Combination Products

This proposal would amend section 505(j) of the FD&C Act to explicitly address the submission and review of drug-device combination products submitted in abbreviated new drug applications (ANDAs), as well as drug products submitted in an ANDA that are used with a device. Currently, section 505(j) of the FD&C Act does not explicitly address ANDAs for drug-device combination products and generic drugs used with a device, and also states that FDA cannot require ANDAs to contain information beyond that set forth in this section. The lack of clarity in certain statutory provisions in this section – which was established nearly 40 years ago at a time when most products were simpler – may, in certain circumstances, make it difficult for companies to develop generic versions of these products and for FDA to efficiently approve ANDAs for these products. As a result, these products, which are often complex products such as autoinjectors and inhalers, can see delayed generic market entry. FDA seeks amendments to clarify, among other things, that FDA can request and review data for such applications, that certain differences between the device constituent parts of the reference listed drug (RLD) and the proposed generic are permissible, and that differences in labeling between the RLD and the proposed generic as a result of permissible differences in the device are also permissible. This proposal would help promote generic competition and reduce the time, uncertainty, and cost of drug development for combination products.

Clarify When Patent Information Must Be Submitted for a 30-Month Stay to Be Available

This proposal would amend provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) to clarify that a 30-month stay of approval of an abbreviated new drug application (ANDA), 505(b)(2) new drug application (NDA), or abbreviated new animal drug application (ANADA) is available only in connection with patents that are submitted by the holder of the brand drug application under section 505(c)(2) or 512(c)(3) of the FD&C Act before the ANDA, 505(b)(2) application, or ANADA is submitted. If a patent is submitted for listing in the Orange Book by the NDA holder before an ANDA or 505(b)(2) application is submitted and, in response to notice of a paragraph IV certification, the NDA holder or patent owner initiates a patent infringement action against the ANDA or 505(b)(2) applicant within 45 days of receiving the required notice, approval of the ANDA or 505(b)(2) application generally will be stayed for 30 months from the

later of the date of receipt of the notice by any owner of the patent or the NDA holder or such shorter or longer time as the court might order. However, if a patent is submitted for listing in the Orange Book after an ANDA or 505(b)(2) application is submitted but before it is approved, the applicant for the pending ANDA or 505(b)(2) application generally must amend its application and provide an appropriate patent certification or statement to the newly listed patent, but no 30-month stay will be available in this circumstance.

Current law is ambiguous with respect to whether patent information submitted as part of the NDA or New Animal Drug Application (NADA) before approval of the brand drug product can give rise to a 30-month stay of approval for an ANDA, 505(b)(2) application, or ANADA submitted after approval of the brand drug product and that relies upon the brand drug product if the ANDA, 505(b)(2) application, or ANADA is submitted before the NDA or NADA holder for the brand drug product has submitted patent information after approval for listing in the Orange Book (for NDAs) or Green Book (for NADAs). This proposal would address that ambiguity.

Creating Parity Between Nicotine and Nicotine Analog in Statute

This proposal would amend section 201 of the Food Drug and Cosmetic (FD&C) Act to define “nicotine analog,” and regulate products containing “nicotine analogs” similar to other tobacco products. Nicotine analogs are a synthetically manufactured class of substances chemically similar to nicotine; however, nicotine analogs currently are not subject to Food and Drug Administration (FDA or the Agency) regulation as a tobacco product. Some manufacturers have marketed and reported using nicotine analogs in tobacco-like products as a way to evade regulation by the FDA. These nicotine analog products—which can be more potent, addictive, and cytotoxic than nicotine, and have a higher abuse liability than tobacco- and synthetic-derived nicotine—are also being marketed in packaging and flavors that are attractive to youth. Defining nicotine analogs as tobacco products (products they are mimicking), provides FDA with clear regulatory authority and allows for enforcement under existing organizational structures.

Require Retention of Data and Records Supporting Marketed Medical Products and Marketed Medical Product Applications and to Address Fraudulent Data

This proposal would provide express authority to ensure that data supporting application and non-application medical products are reliable and verifiable for as long as the product may be legally marketed, and to ensure that FDA has appropriate tools to act on findings of fraudulent or unreliable data, including untrue statements of material fact, during premarket review and across the total product life cycle. FDA is increasingly identifying instances of fraudulent or unreliable data provided in premarket submissions for medical devices, in marketing applications for drug and biological products, and on inspection of manufacturing establishments or through remote regulatory assessments for both application and non-application medical products (e.g., OTC monograph drugs). In many instances, the fraudulent or unreliable nature of the data is not discovered until after marketing authorization is granted or a non-application medical product is distributed. This may be because the nature of the unreliable data is not apparent until after an

inspection is conducted or a pattern is discovered. Past instances of product submissions supported with falsified data – which have affected a range of products across the medical device risk spectrum – put U.S. consumers at risk and result in a competitive disadvantage for U.S. medical product manufacturers, as the firms involved in these issues are often based in China. These new or clarified authorities would help protect the public from medical products that have not been shown to be safe and effective and would enhance the FDA’s ability to address bad actors who operate at the expense of domestic firms who conduct due diligence in their FDA submissions.

Authorize the Disclosure and Use of Certain Information Related to Impurities in Drugs That Pose a Risk to Human and Animal Health

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

Postapproval Quality Updates

This proposal would grant FDA express authority to require drug applicants to submit a postapproval quality update to provide additional information on, or propose or report on changes needed to ensure, ongoing quality (e.g., compliance with Current Good Manufacturing Practice requirements), and therefore, help ensure ongoing safety and efficacy, of the drug product once approved and marketed. Express authority to require actions to address residual quality risks in the postapproval period will complement FDA’s risk-based surveillance inspections and allow FDA to receive timely updates on applicants’ actions to address residual risk and facilitate FDA’s ability to identify and take appropriate enforcement actions related to adulterated products. This proposal would apply to applicants submitting NDAs, ANDAs, NADAs, ANADAs, and BLAs and would not change the statutory premarket approval standard.

Modernizing the Requirements in BPCA and PREA for Agency Review of Pediatric Postmarket Safety Reporting

This proposal would remove the time-based requirement for postmarket safety reviews in the Best Pharmaceuticals for Children Act (BPCA) and Pediatric Research Equity Act (PREA), allowing FDA to dedicate resources to real-time, risk-based surveillance activities conducted as safety signals emerge and to maximize the efficiency and focus of Pediatric Advisory Committee (PAC) deliberations. BPCA and PREA (sections 505A(l) and 505B(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)) require that “the Secretary shall ensure that all adverse event reports that have been received for such drug (regardless of when such report was received) are referred to the Office of Pediatric Therapeutics” and that “the Director of such Office shall provide for the review of the reports by the Pediatric Advisory Committee” 18 months after a BPCA-related or PREA-related labeling change. The duplicative, resource-intensive adverse-event review requirement in the statutes should be removed because the Agency’s existing modern risk-based approach to postmarket safety surveillance already ensures that the purpose of these sections of BPCA and PREA to fully and appropriately monitor the postmarketing safety of drugs and biological products in children is achieved. This modification would yield a less burdensome, more efficient, and equally effective risk-based approach that incorporates modern informatic technologies.

Share Food Safety Information with State, Local, Tribal, and Territorial Authorities

This proposal would amend sections 708 and 301(j) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 379 and 331(j)), to authorize FDA to share certain food-related information with state, local, Tribal and U.S. territorial authorities, to improve speed, efficiency and promote collaboration to protect the public health. The proposal would also amend these provisions of the FD&C Act to prohibit the public disclosure by these entities of information provided by FDA that is trade secret information or confidential commercial information. Authorizing FDA to share real-time information such as foodborne illness surveillance data, laboratory sampling testing information, inspectional information and results, distribution lists for recalls and outbreaks, manufacturing equipment and processing information, consumer complaints, and other information the Secretary deems necessary, while prohibiting further disclosure, will assist FDA and regulatory partners to protect the public and Make America Healthy Again.

Disrupt the Flow of Problematic Imported Medical Devices

FDA is seeking additional authorities that would give the Agency greater assurances that foreign firms are manufacturing devices intended for import into the United States in compliance with quality systems requirements. In addition, FDA is seeking additional authorities to address when the Agency becomes aware that shipments of devices from a particular country, territory, or region may be adulterated, misbranded, or otherwise violative, and pose a threat to U.S. healthcare providers and patients. Despite extensive efforts utilizing all of FDA’s existing

oversight authorities, the United States continues to see an influx of problematic imported devices from China and other nations that puts patients and healthcare providers at substantial risk of harm. This compromises the U.S. healthcare system and the supply chain for critical medical devices upon which our hospitals, providers, and patients depend. This risk from problematic imported devices is particularly concerning in outbreak situations when supplies are limited and the U.S. healthcare system is more vulnerable to reliance on foreign suppliers and imported products that may not meet premarket and postmarket requirements under the Federal Food, Drug, and Cosmetic Act (FD&C Act). This poses a substantial national security risk and diminishes U.S. preparedness. These new authorities will enhance FDA's ability to ensure safety, effectiveness, and quality of medical devices entering the U.S. market, support patient health and safety, and advance U.S. preparedness and national security.

Clarify FDA's Enforcement Authority Regarding Manufacturing Changes to Approved Drugs and Biological Products

This proposal would clarify FDA's ability to enforce requirements related to manufacturing changes to drugs and biological products. Major manufacturing changes, such as using a different manufacturing facility or supplier of an active pharmaceutical ingredient (API) than specified in an FDA-approved application or license, have substantial potential to adversely affect the safety or effectiveness of a drug or biological product. The proposal is intended to ensure that, if a manufacturer makes a change to the manufacturing process, patients are not exposed to that drug until the change has been appropriately validated and, if the change is a major change, FDA has reviewed and approved the manufacturing change. FDA proposes to revise various sections of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and Public Health Service Act (PHS Act) to clarify FDA's ability to enforce requirements related to manufacturing changes for drugs approved under the FD&C Act and biological products licensed under the PHS Act.

Align the FD&C Act with Longstanding Timelines and Procedures Governing Application Reviews and Streamline Appeals When an application is Not Approvable

FDA proposes to amend the FD&C Act to codify longstanding timelines and procedures that are central to FDA's review of new drug applications (NDAs) and abbreviated new drug applications (ANDAs). Specifically, FDA proposes to amend subsections 505(c) and (j) of the FD&C Act (21 U.S.C. 355(c) and (j)) to remove the 180-day timeframe to either approve the application or give the applicant notice of an opportunity for a hearing (NOOH) on whether the application is approvable. FDA proposes to reference the goals identified in commitment letters under the Prescription Drug User Fee Act (PDUFA) and Generic Drug User Fee Amendments (GDUFA). FDA also proposes to amend section 505(c) and (j) of the FD&C Act to expressly include (1) the filing and receipt determinations described in FDA's regulations and (2) FDA's longstanding complete response letter (CRL) procedures. FDA further proposes to enhance efficiency by replacing the hearing-related processes described in section 505(c) and (j) of the FD&C Act with an appeal process modeled after the expedited withdrawal procedures for accelerated approval described in section 506(c)(3)(B) of the FD&C Act.

Provide Medical Assistance and Evacuation Insurance for Food and Drug Administration (FDA) Employees

Existing HHS authorities do not permit FDA to purchase medical assistance and evacuation insurance coverage for full-time federal, uniformed, and intermittent FDA employees on official government foreign travel. As a result, travel-related medical assistance insurance when needed in an emergency is considered a personal expense and must therefore be borne by the employee. Absent this coverage, the employee must cover the costs of medical emergencies when on official travel overseas – which can be substantial. Factors such as the employee covering unforeseen foreign medical expenses and foreign travel insurance affect morale and affect an employee’s willingness to conduct foreign travel to support mission requirements. In addition, these factors may also deter outside candidates from joining the Federal Government. Specifically, as it relates to FDA, we are seeking this authority to permit the purchase of medical assistance and evacuation insurance coverage for FDA employees on official government foreign travel. The ability to provide medical assistance and evacuation insurance for FDA’s employees, especially those investigators conducting foreign inspections on multiple week trips on multiple occasions during a calendar year, will better support employees by providing points of contact for medical emergencies, ensuring that the employee receives appropriate medical care, and ensuring that expenses are paid when needed in a timely fashion. For example, at FDA, during the decade leading up to the COVID-19 pandemic, foreign inspections almost quadrupled (from 1,102 in FY 2010 to 3,766 in FY 2019). The number of foreign inspections has steadily increased to pre-COVID numbers with employees from FDA’s Office of Inspections and Investigations (OII) conducting 2,790 foreign inspections in FY2023 and 3,623 foreign inspections in FY 2024. These employees conducting the inspections typically travel overseas approximately once or twice a year for 3-4 weeks. In addition, this insurance can serve as a retention tool for staff fulfilling mission requirements and act as a recruitment tool for those conducting foreign healthcare missions.

Create a new Clinical Trial Notification Pathway to Serve as an Alternative to the Burdensome Existing Investigational New Drug Pathway to accelerate drug development timeline to Make America Healthy Again

Revise the Food and Drug Administration (FDA) regulatory framework to create an optional, risk-based Expedited IND pathway for certain Phase 1 clinical trials where there is existing preclinical data that can potentially satisfy the regulatory standard with validated NAMS methods. This new pathway, which would serve as alternative to the existing Traditional Investigational New Drug (IND) pathway, aims to reduce duplicative and time-consuming requirements while maintaining safety and ethical standards. This policy would be particularly important for smaller biotechnology firms that face greater barriers to entry under the current paradigm, which has fueled the increase in early stage preclinical, and Phase 1 activity in China and Australia. The U.S. has longer timelines and a greater regulatory burden because of the preclinical work and investigational process – this policy would create an accelerated path to

initiate U.S.-based Phase 1 clinical programs, drive market competition by reducing the regulatory burden for drugs with adequate preclinical data to support first-in-human studies, and lower drug development costs in support of the President’s goals on reshoring industry. The goal of this new pathway is to accelerate the drug development timeline and encourage U.S. biotechnology investment – in line with the President’s actions to onshore the pharmaceutical industry. This type of reform is also a “do out” of the White House’s Make Our Children Healthy Again: Strategy Report (September 2025), and aligned with the Administration’s deregulatory efforts. The alternative Expedited IND would also have the added benefit of lessening animal testing, because much of the data in the IND is duplicative of preclinical animal studies. This proposal would be added by amending section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) to add the new Expedited IND model.

Give FDA significant enforcement authorities, including civil monetary penalties and the authority to pull products off of market if active pharmaceutical ingredient source data is not reported.

Current law and regulations (see, e.g., 21 CFR 314.50) require that applicants including information about the API, including the facilities in which it’s manufactured) in the application. FDA will not approve an application (NDA, ANDA, BLA) if this information is not included. FDA is requesting a revision to section 510(j)(3) of the FD&C Act to impose Civil Monetary Penalties on Finished Dosage Form (FDF) manufacturers who fail to disclose how much API is used from each API manufacturer approved in the application. The lack of connection between API and FDF reporting hinders the ability for FDA to have full visibility into the supply chain. Making this change in law will help create a more sustainable supply chain and achieve the President’s goal of Making America Healthy Again.

Permanently authorize the rare pediatric disease priority review voucher program and related user fees.

This proposal would permanently reauthorize the Rare Pediatric Disease (RPD) Priority Review Voucher (PRV) program, creating more predictability for sponsors and ensuring children living with debilitating or life-threatening conditions have access to safe and effective therapies. The RPD PRV program aims to incentivize drug development for rare pediatric diseases by awarding priority review vouchers to certain approved rare pediatric disease product applications. Specifically, Section 529 of the FD&C Act (21 U.S.C. 360ff) authorizes FDA to award priority review vouchers that entitles the holder of a voucher to shorten a review timeline from 10 months to 6 months. Eligible products must contain a new active moiety and be intended to prevent or treat a rare pediatric disease that is serious or life-threatening. The program has historically been reauthorized every 4 years, although it had recently been partially lapsed since 2024. It is set to expire again in 2029.

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 work to reverse 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.

FDA’s related field activities conduct rigorous, transparent, and science-based inspections and investigations, collect samples for analyses of regulated products, conduct emergency response, consumer compliant follow up, recall activities and review imported products offered for entry into the United States. Within the field laboratories, FDA performs scientific testing on regulated products in support of inspectional and compliance operations, contributes to applied research, and assists in criminal investigations.

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Human Foods	1,207,864	1,182,768	1,192,004	1,184,725	1,293,226	108,501
<i>Budget Authority</i>	1,196,097	1,170,765	1,179,319	1,171,319	1,279,788	108,469
<i>User Fees</i>	11,767	12,003	12,685	13,406	13,438	32
FTE	3,969	4,024	4,024	3,999	4,049	50

Figure 10 – Human Foods Funding History Table

The FY 2027 Budget for the HFP total is \$1,293,226,000 including \$1,279,788,000 in budget authority and \$13,438,000 in user fees. The budget authority increased by \$108,469,000 and \$32,000 in user fees compared to the FY 2026 Enacted level.

The FY 2027 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 2027 President's Budget: Human Foods <i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	1,171,319
FY 2027 Budget Authority Changes	108,469
MAHA	25,000
Global Competitiveness and Inspection Capability	18,000
Reduction of the Federal Bureaucracy	65,469
FY 2027 Budget Net Total: Human Foods	1,279,788

Figure 11 – Human Foods Budget Authority

Total Budget Authority Changes +\$108.5 million / +50 FTE

MAHA: +\$25.0 million / +30 FTE

Remove Unsafe Chemicals from Food: (+\$25.0 million / +30 FTE)

The FY 2027 Budget provides \$57.0 million across FDA programs to support the Secretary’s vision to remove harmful chemicals from the food supply by addressing unsafe chemical additives used in food. It will expand Closer to Zero to eliminate toxic elements from foods consumed by children and develop a compliance system to test naturally derived food colors for elemental contaminants including lead, mercury, arsenic, and cadmium. FDA requires funding to invest in addressing food safety gaps, such as developing models to predict levels of PFAS in food-producing animals. The initiative will also explore ways legislative changes can be used to close the GRAS loophole. \$25.0 million of this funding will be for HFP.

Global Competitiveness & Inspection Capabilities: +\$18.0 million / +20 FTE

Domestic Food Safety Inspection (+\$9.0 million / 0 FTE)

The FY 2027 Budget provides \$9.0 million to HFP to support transitioning routine domestic food safety inspections to states and requires funding towards this effort. To strengthen the national food safety system, FDA is expanding current state agreements for routine inspections of domestic food facilities to all applicable domestic facilities. To advance the Better Regulatory Inspections for Dynamic Government Efficiency (BRIDGE) Project, HFP will fund additional states with sufficient inspection infrastructure to implement the tiered inspection model and standardized protocols.

Increase Foreign Inspection Capacity: (+\$9.0 million / +20 FTE)

The 2027 Budget provides \$9.0 million to increase the agency's inspection capacity, safeguard U.S. consumers and patients, and reinforce FDA's global leadership. FDA's inspections and investigations ensure that Americans have timely access to safe and effective food and medical products. Increasing OII's inspectional capabilities directly supports the Administration's economic priorities as well as the Administration and HHS Secretary's MAHA priorities. Enhancing post-marketing surveillance, real-world data, large-scale lifetime interventions with trials, and alternative testing models are all supported and strengthened using OII's inspectional and investigational activities and are priorities for the Commissioner.

Reduction to the Federal Bureaucracy: +\$65.5 million / 0 FTE

In line with the administration's efforts in the FY 2026 President's Budget to reduce the federal bureaucracy and consolidate to core functions, this budget reflects previously accounted adjustments across the agency and MAHA priorities. These actions resulted in a net increase for the HFP in alignment with MAHA priorities and contract consolidation.

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.
- In 2025, in line with the administration and agency priorities to phase out synthetic, petroleum-based dyes from the nation's food supply, FDA approved four new color additive petitions, expanding the palette of available colors made from natural sources for manufacturers to safely use in food.¹
- In June 2025, FDA released for public comment its proposed method for ranking chemicals in the food supply—providing a transparent, systematic, and science-based approach to determining which chemicals the agency would prioritize for post-market assessments through the agency's post-market chemical review program.²
- In June 2025, FDA issued a Request for Information (RFI) to begin the nutrient review process required by law for infant formula – this was a critical step in Operation Stork Speed– a groundbreaking initiative to ensure the safety, reliability, and nutritional adequacy of infant formula for American families. While the FDA regularly reviews individual nutrient requirements for infant formula, this will be the first comprehensive review since 1998.³
- In July 2025, FDA and USDA announced a joint RFI to gather information and data to help establish a federally recognized, uniform definition for “ultra-processed foods”—a critical step in providing increased transparency to consumers about the foods they eat.⁴

¹ <https://www.fda.gov/news-events/press-announcements/fda-approves-gardenia-genipin-blue-color-additive-while-encouraging-faster-phase-out-fdc-red-no-3>

² <https://www.fda.gov/food/hfp-constituent-updates/fda-seeks-input-new-method-ranking-chemicals-food-post-market-assessments>

³ <https://www.fda.gov/news-events/press-announcements/hhs-fda-initiate-comprehensive-review-nutrients-infant-formula>

⁴ <https://www.fda.gov/news-events/press-announcements/hhs-fda-and-usda-address-health-risks-ultra-processed-foods>

- In July 2025, FDA announced its intent to revoke 52 food standards after concluding they are outdated and unnecessary to increase transparency and remove regulations that have outlived their purposes.
- In August 2025, FDA issued a proposed rule that would update the standard of identify for pasteurized orange juice. If implemented, the change is estimated to save domestic orange juice manufacturers more than \$50 million per year and reduce reliance on foreign imports.
- In 2025, FDA triaged over 15,000 complaints about illness, injury, allergic reaction, or other health-related issue or about defects in the quality or safety of an FDA-regulated food, dietary supplement, or cosmetic product and responded to nearly 24,000 inquiries from consumers, industry, regulatory partners, medical professionals, and other stakeholders through FDA’s Food and Cosmetic Information Center (FCIC).
- In December 2025, FDA issued warning letters [to improve recall effectiveness](#), following an infant botulism outbreak linked to ByHeart infant formula, after retailers failed to remove recalled products from store shelves in over 175 locations across 36 states.
- Completed proactive food risk management and improved the detection of and mitigation of pathogens, specifically *Salmonella enteritidis* (SE) in more than 345,000 dozen shell eggs through the swift and comprehensive completion of focused complex egg investigations.
- Worked across government to protect the safety and integrity of FDA regulated products and improved the detection of harmful ingredients and unsafe food additives. For example, in collaboration with U.S. Marshals and Department of Justice, FDA completed three complex high-risk inspections and issued administrative detention orders at three separate firms within 24 hours and worked to seize approximately \$1 million of unsafe products.
- Enhanced food supply chain integrity with the addition of almost 30 foreign suppliers to import alerts for violations identified during Foreign Supplier Verification Program inspections. These actions resulted in the immediate detainment of shipments of specific products from specific firms without use of agency resources because the inspections provided sufficient evidence that the goods violated FDA regulations.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

PERFORMANCE

The Human Foods Program’s performance measures focus on, regulatory science activities and postmarket inspection and import screening activities to ensure the safety and proper labeling of the America food supply and cosmetics, as detailed in the following table. 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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
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 2025: 87.5 Target: 80.0 (Target Exceeded)	80.0	80.0	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 2025: 995 Target: 989 (Target Exceeded)	1,008	1,023	+15 null
214221 Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 98% Target: 65% (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 2025: 76% Target: 50% (Target Exceeded)	50%	50%	Maintain
214337 Accuracy rate for confirmation of presumptive STEC positives from leafy green samples. (Output)	FY 2025: 50% Target: 60% (Target Not Met)	50%	50%	Maintain
214305 Increase laboratory surge capacity in the event of terrorist attack on the food supply. (Radiological and	FY 2025: 3,200 rad & 2,600 chem Target: 3,200 rad & 2,600	3,200 rad & 2,600 chem	3,200 rad & 2,600 chem	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
chemical samples/week). (Outcome)	chem (Target Met)			

Figure 12 - Foods Performance Table

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

Leafy Green Samples

Leafy greens are widely consumed and an important part of a healthy diet, but they have also been repeatedly linked to illnesses caused by Shiga toxin-producing *E. coli* (STEC). To help prevent recurring outbreaks, the FDA is improving its testing methods to more quickly and accurately detect and confirm STEC in leafy greens. FDA microbiologists are enhancing the microbiological workflow used to test for STEC, which will improve confirmation accuracy and increase the ability to isolate harmful strains when they are present. A key investment is a new STEC-specific agar used during the confirmation step. This agar is expected to raise FDA’s confirmation rate from about 30 percent to more than 70 percent over the next few years, strengthening confidence in screening results and improving public health risk assessment. These improvements will allow FDA to identify and address potential contamination issues in leafy greens and other short shelf-life produce before products reach consumers. Progress depends on access to the STEC-specific agar supplied by an industry partner under a research collaboration agreement. Production was temporarily disrupted in FY 2025 due to a facility move, resulting in FDA missing the target by 10 percent. STEC-specific agar production is expected to remain limited through FY 2026. Despite this, FDA anticipates continued progress in the evaluation of this confirmation method and is targeting a 50 percent confirmation rate for FY 2026 and FY 2027.

HUMAN DRUGS

PROGRAM DESCRIPTION

FDA's Human Drugs Program, including 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 and biosimilar 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 submission and assessment process through modernization, expediting patient access to safe and effective medications. This includes forward-looking initiatives like the FDA PreCheck that will help accelerate the establishment of high-quality pharmaceutical manufacturing facilities in the United States through enhanced early engagement and streamlined assessment processes. The PreCheck initiative complements the [FRAME initiative](#), which supports the adoption of advanced manufacturing technologies and strategic use of data. FDA continues to uphold and enhance gold-standards to prevent medication errors and promote public health through safe and effective drugs.

FDA 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, ensuring high-quality, affordable generic and biosimilar drugs are available to the American public, promoting awareness of the safety and efficacy of generic and biosimilar drugs through various outreach efforts, monitoring post-market safety and addressing substance abuse and overdose prevention.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Human Drugs	2,283,747	2,338,496	2,428,505	2,497,984	2,537,182	39,198
<i>Budget Authority</i>	761,494	719,679	724,168	684,841	631,818	-53,023
<i>User Fees</i>	1,522,253	1,618,817	1,704,337	1,813,143	1,905,364	92,221
FTE	6,953	7,542	8,057	6,929	6,952	23

Figure 13 - Human Drugs Funding History Table

The FY 2027 Budget for the Human Drugs Program is \$2,537,182,000, including \$631,818,000 in budget authority and \$1,905,364,000 in user fees. The budget authority decreased by \$53,023,000 and user fees increased by \$92,221,000 compared to the FY 2026 Enacted level.

The FY 2027 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 2027 President's Budget: Human Drugs	
<i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	684,841
FY 2027 Budget Authority Changes	(53,023)
Operation Imperatives	24,200
Global Competitiveness and Inspection Capability	14,000
Reduction of the Federal Bureaucracy	(91,223)
FY 2027 Budget Net Total: Human Drugs	631,818

Figure 14 - Human Drugs Budget Authority

Total Budget Authority Changes: -\$53.0 million / +23 FTE

Operational Imperatives: +\$24.2 million / 0 FTE

Protecting User Fee Agreements on Spending and Appropriations Triggers: (+\$24.2 million / 0 FTE)

FDA’s request includes \$41.6 million agencywide to protect user fee agreements. This funding is mandatory and required for FDA to be able to continue to collect and spend user fees as required by statutory mandates. Failure to meet these funding thresholds delay critical program activities and cause significant harm to FDA’s operations, stakeholders, and the American public. The Human Drugs Program requests \$24.2 million for this initiative.

Global Competitiveness & Inspection Capabilities: +\$14.0 million / +23 FTE

Improving Inspectorate Capabilities: (+\$5.0 million / +4 FTE)

FDA requests \$9.0 million to increase agencywide inspection capacity, safeguard U.S. consumers and patients, and reinforce FDA’s global leadership. FDA’s inspections and investigations ensure that Americans have timely access to safe and effective food and medical products. Increasing FDA’s inspectional capabilities directly supports the Administration’s economic priorities as well

as the Administration and HHS Secretary's MAHA priorities. Enhancing postmarket surveillance, real-world data, large-scale lifetime interventions with trials, and alternative testing models are all supported and strengthened using FDA's inspection and investigational activities and are priorities for the Commissioner. The Human Drugs Program requests \$5.0 million for this initiative.

Accelerate Advanced Pharmaceutical Manufacturing: (+\$9.0 million / +19 FTE)

FDA will improve the nation's global competitiveness by funding opportunities for scientific advancement and streamlining. Initiatives include accelerating review and approval by supporting the Commissioner's National Priority Voucher program and developing science- and risk-based approaches to streamline CMC reviews. It will also fund FDA PreCheck, a two-phase initiative proposed to accelerate the establishment of new or advanced pharmaceutical manufacturing facilities in the United States, strengthening the domestic drug supply chain.

Reduction to the Federal Bureaucracy: -\$91.2 million / 0 FTE

In line with the administration's efforts to reduce the federal bureaucracy and FDA's FY 2026 President's budget submission, this budget reflects \$244.8 million of previously accounted funding reductions across the agency. Previously accounted FTE reductions were reflected in the FY 2026 Enacted Bill.

USER FEES

Current Law User Fees: +\$92.2 million

The Human Drugs Program request includes an increase of \$92.2 million for user fees, compared to FY 2026 Enacted level, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM 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:

- CDER issued and completed a safety labeling change for opioid analgesics to better emphasize the risks associated with their long-term use, communicate the risks of addiction, misuse, and overdose during long-term use, and strengthen warnings that higher doses come with greater risks.
- In January 2025, CDER and CBER released the [FDA Rare Disease Innovation Hub Strategic Agenda](#) which outlines the actions the [Rare Disease Innovation Hub \(RDIH\)](#) would take in its first full year to support rare disease drug development.
- To date in FY 2025, CDER published 36 [guidances to industry](#), including one on the use of [AI to support regulatory decision](#) making, and one developed in collaboration with international regulators on the [inclusion of pregnant and breastfeeding women in clinical trials](#).

- In CY 2024, FDA worked with manufacturers to successfully prevent 268 shortages, expedited review of 206 submissions, and prioritization of 20 inspections. In August 2025, FDA announced the resolution of the IV saline solution shortage.
- To date in FY 2025, CDER issued 247 warning letters, classified 317 drug recall events totaling 677 recalled drug products, and added 93 products to FDA import alert to help potentially unsafe products from entering the U.S. supply chain.
- FDA field laboratories supported the FDA's first successful prosecution of distributing counterfeit GLP-1 products and has led to other enforcement actions including product recalls, warning letters, and import alerts. FDA laboratories also screen products at international mail facilities to remove potentially dangerous items like illegal opioids before they reach the public.
- FDA collaborated with the Department of War, the Strategic National Stockpile, and other federal agencies to test life-saving emergency medicines like antivirals and chemical antidotes to determine if they remain safe and effective past their labeled expiration dates. This Shelf-Life Extension Program (SLEP) saved the U.S. government over \$5 billion in FY 2025 by extending the usable life of stockpiled medications instead of replacing them. The testing ensures that emergency medicines stored for public health crises remain safe and effective when Americans need them most.
- Disrupted the supply chain of unapproved drugs by intercepting more than one million tablets and capsules of unapproved drugs including opioids. This high impact work to deliver a healthier future for Americans also secured more than \$231 million in criminal penalties for misbranding and improper marketing of opioid medications.
- Delivered a more secure drug supply chain for Americans with the refusal of more than 72,000 violative drugs products offered for import and the destruction of more than 12 million tablets/capsules valued at over \$4 million. Further enhanced the U.S. drug supply chain through numerous complex joint operations with Customs and Border Protection resulting in the destruction, seizure, or exportation of 331,043 capsules, tablets, and pills with a declared value of \$486,256.
- Increased regulatory harmonization with international partners to increase consistency, reduce barriers for innovation, and increase safety and efficacy of FDA regulated products entering the United States by leveraging inspections completed by regulatory partners resulting in approximately \$21 million in estimated resource savings.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
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 2024: 96% 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 2023: 93% 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 2024: 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 2024: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
223216 Review and act on 90 percent of priority original Abbreviated New Drug Application (ANDA) submissions within the required timeframe. (Output)	FY 2023: 93.0% Target: 90.0% (Target Exceeded)	90%	90%	Maintain
223235 Review and act on 90 percent of standard original Abbreviated New Drug Application (ANDA) submissions within the required timeframe. (Output)	FY 2023: 94.0% Target: 90.0% (Target Exceeded)	90%	90%	Maintain
224221 Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 89% Target: 65% (Target Exceeded)	65%	65%	Maintain
224222 Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 44% Target: 40% (Target Exceeded)	40%	40%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
292203 Number of medical product analyses conducted through FDA's Sentinel Initiative. (Output)	FY 2025: 55 Target: 65 (Target Not Met)	50	50	Maintain

Figure 15 - Human Drugs Performance Table

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

New Generic Drugs

Generic drug user fees make it possible for FDA and industry to continue to ensure that the American public has access to safe, effective and high-quality generic drugs. The implementation of the Generic Drug User Fee Amendments (GDUFA) encompasses a wide range of activities that fall within the scope of regulating the generic drug industry. GDUFA was reauthorized on September 30, 2022 (GDUFA III), with provisions that are in effect from October 1, 2022, through September 30, 2027. The performance goals and program enhancements specified in the GDUFA III commitment letter apply to aspects of the generic drug assessment program and build on the GDUFA program established and enhanced through previous authorizations. New enhancements to the program are designed to maximize the efficiency and utility of each assessment cycle, with the intent to reduce the number of assessment cycles for abbreviated new drug applications (ANDAs) and facilitate timely access to quality, affordable, safe and effective generic medicines. Certain new enhancements are specifically designed to foster the development, assessment, and approval of complex generic products. FDA is committed to meeting the performance goals and to continuous improvement of FDA’s performance.

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 Prescription Drug User Fee Act (PDUFA) program is to increase the efficiency and effectiveness of the first review cycle and decrease the number of review cycles necessary for approval. In FY 2023, CDER missed one of its performance targets associated with the review of non-NME original NDA submissions. CDER received 18 original priority non-NME NDAs subject to the PDUFA goal dates. CDER saw an increase of 21 percent in original marketing application submissions between FY 2022 and FY 2023, with a 64 percent increase in the number of non-NME NDAs. This review work, in addition to other regulatory work, contributed to a sustained high workload that impacted performance.

Sentinel Initiative

The Sentinel Initiative Program monitors the safety of FDA-regulated medical products by using a distributed data network of electronic health and claims data. In FY 2025, FDA missed the target by 10 medical product analyses conducted.

Human and Animal Drug Follow-Up Inspections

In FY 2024, 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. This measure tracks follow-up inspections that occur after a firm is out of compliance following the receipt of an original Official Action Indicated (OAI) inspection classification. When FDA conducts a follow-up inspection after the original OAI classified inspection, the firm must receive a Voluntary Action Indicated (VAI) or No Action Indicated (NAI) inspection classification for it to be considered compliant. The inspection classification falls out of the FDA hands and into the firm's hands as to addressing and making the corrections from the original OAI.

BIOLOGICS

PROGRAM DESCRIPTION

The Biologics Control Act of 1902 established the Biologics Program in the Department of Treasury’s Hygienic Laboratory, which became part of the National Institutes of Health (NIH) in 1930. In 1972, the Biologics Program transferred from NIH to FDA and is currently comprised of the Center for Biologics Evaluation and Research (CBER) and the Office of Inspections and Investigations’ (OII) biologics field program. CBER’s 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. CBER makes recommendations to vaccine manufacturers for the virus strains to be used in influenza vaccines annually. Through its mission, CBER also seeks to protect the public against the threats of emerging infectious diseases and bioterrorism. CBER uses sound science and regulatory expertise to:

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

FDA’s related field activities conduct rigorous, transparent, and science-based inspections and investigations, collect samples for analyses of regulated products, conduct emergency response, consumer complaint follow up, recall activities and review imported products offered for entry into the United States. Within the field laboratories, FDA performs scientific testing on regulated products in support of inspectional and compliance operations, contributes to applied research, and assists in criminal investigations.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Biologics	490,465	571,811	607,060	601,291	574,096	-27,195
<i>Budget Authority</i>	272,215	268,068	268,197	259,295	206,985	-52,310
<i>User Fees</i>	218,250	303,743	338,863	341,996	367,111	25,115
FTE	1,467	1,641	1,730	1,549	1,556	7

Figure 16 – Biologics Funding History Table

The FY 2027 Budget for the Biologics Program is \$574,096,000 of which \$206,985,000 is budget authority and \$367,111,000 is user fees. The budget authority decreased by \$52,310,000 and user fees increased by \$25,115,000 compared to the FY 2026 Enacted level.

The FY 2027 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 2027 President's Budget: Biologics	
<i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	259,295
FY 2027 Budget Authority Changes	(52,310)
Global Competitiveness and Inspection Capability	2,000
Reduction of the Federal Bureaucracy	(54,310)
FY 2027 Budget Net Total: Biologics	206,985

Figure 17 – Biologics Budget Authority

Total Budget Authority Changes: -\$52.3 million/ 7 FTE

Global Competitiveness/Inspection Capability: +\$2.0 million / +7 FTE

Improving Inspectorate Capabilities: (+\$2.0 million/ +7 FTE)

FDA requests \$9.0 million to increase agencywide inspection capacity, safeguard U.S. consumers and patients, and reinforce FDA's global leadership. The Biologics Program requests \$2.0 million to support this initiative. FDA's inspections and investigations ensure that Americans have timely access to safe and effective food and medical products. Increasing FDA's inspectional capabilities directly supports the Administration's economic priorities as well as the Administration and HHS Secretary's MAHA priorities. Enhancing postmarket surveillance, real-world data, large-scale lifetime interventions with trials, and alternative testing models are all supported and strengthened using FDA's inspection and investigational activities and are priorities for the Commissioner.

Reduction to the Federal Bureaucracy: -\$54.3 million / 0 FTE

In line with the administration's efforts to reduce the federal bureaucracy and FDA's FY 2026 President's budget submission, this budget reflects \$244.8 million of previously accounted reductions across the agency. Previously accounted FTE reductions were reflected in the FY 2026 Enacted Bill.

USER FEES

Current Law User Fees: +\$25.1 million

The Biologics Program request includes an increase of \$25.1 million for user fees, compared to FY 2026 Enacted level, which will allow FDA to fulfill its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM ACCOMPLISHMENTS

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 September 2025, FDA introduced the [Rare Disease Evidence Principles](#) to provide greater speed and predictability in the review of therapies intended to treat rare diseases with very small patient populations with significant unmet medical need and that are driven by a known genetic defect.
- In support of promoting meaningful cures for U.S. patients, CBER approved the first gene therapy treatment for Wiskott-Aldrich syndrome, the first cellular therapy for severe aplastic anemia, and the first CAR-T therapy for marginal zone lymphoma in December 2025.
- [FDA's Rare Disease Program](#) continues to advance the development of new and innovative biological products; as of the end of FY 2025, FDA's Biologics Program granted 87 Breakthrough Therapy designations, with 36 of the products having Orphan Drug Designation. From CY 2011 through CY 2025, there have been 59 novel biologic approvals with orphan designation.
- Since the program's inception in December 2016, FDA has granted 193 Regenerative Medicine Advanced Therapy (RMAT) designations agencywide as of the end of September 2025.
- For FY 2025, FDA's Biologics Program documented 0 new product shortages, 44 prevented shortages, 22 ongoing shortages, and 59 notifications from 37 different manufacturers.
- FDA Biologics Program's full approval list for [2024](#) and [2025](#) are available on its [website](#).
- Enhanced the resilience and security of the biological product supply chain with the completion of numerous scientifically complex inspections to successfully support pre-licensing for several biomanufacturing facilities leading to product approvals or cleared manufacturing processes.
- Strengthened the biological product supply chain and accelerated cures to meet emerging public health needs through completion of numerous complex and scientifically challenging inspections to support four applications in the National Priority Voucher Program.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
231301 Percentage of Lot Distribution Reports that were entered into the Regulatory Management System – Biologics License Applications (RMS-BLA) within 7 Days. (Output)	FY 2024: 98% Target: 85% (Target Exceeded)	85%	85%	Maintain
233205 Complete review and action on complete blood bank and source plasma BLA submissions within 12 months after submission date. (Output)	FY 2024: 50% Target: 90.0 (Target Not Met)	90%	90%	Maintain
233206 Complete review and action on complete blood bank and source plasma BLA supplements within 12 months after submission date. (Output)	FY 2024: 98.0 Target: 90.0 (Target Exceeded)	90%	90%	Maintain
233207 Review and act on standard New Molecular Entity (NME) 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 6 months of the 60-day filing date. (Output)	FY 2024: 88% Target: 90% (Target Not Met)	90%	90%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
233211 Review and act on new non-user fee, non-blood product applications within 12 months of receipt. (Output)	FY 2022: 0% ⁵ Target: 60% (Target Not Met)	60%	60%	Maintain
234101 Increase manufacturing diversity and capacity for influenza vaccine production. (Output)	FY 2024: Continued evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes. Target: Continue evaluation of new methods to produce more stable high-yield influenza vaccine reference strains and improve current manufacturing processes (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	N/A
234221 Percentage of Biologics significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 75% Target: 55% (Target Exceeded)	55%	55%	Maintain
234222 Percentage of Biologics follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 79% Target: 50% (Target Exceeded)	50%	50%	Maintain

⁵ CBER received only one new non-user fee, non-blood product BLA during FY 2022. This application is currently in "Complete Response Letter" status because of inspectional issues, and it took longer than expected to incorporate the findings from the inspection into the review of the application. Although we missed this goal, CBER plans to keep the targets the same moving forward.

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
253221 Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 100% Target: 50% (Target Exceeded)	50%	50%	Maintain

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

Blood BLA Submissions

In FY 2024, CBER filed two new Blood Bank and Source Plasma BLA submissions where only one submission missed the goal date. The Applicant and CBER agreed that it would be better for the applicant to withdraw (WD) this BLA and submit a new BLA due to issues that came to light during the review process. Despite several documented communications, the applicant did not submit its WD request until after the goal date. Although this measure was missed, CBER plans to keep the targets the same moving forward.

Priority BLA Submissions

Although CBER routinely meets its PDUFA performance goals, CBER fell slightly short (88 percent) on the FY 2024 target to review and act on 90 percent of the Priority NME NDA and original BLA submissions within six months of the 60-day filing date. CBER filed eight original BLAs with priority schedules where only one submission missed the user fee goal date. An amendment was received containing new information for this submission. The review team designated it as a major amendment which would add three months to the schedule. However, the applicant objected and the CBER Center Director concurred. The schedule was reverted to the original priority milestones. The review team was unable to complete the review and actions by the user fee goal date. CBER will strive to meet the target of 90 percent, as established in the PDUFA commitment letter.

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, 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.

FDA’s related field activities conduct rigorous, transparent, and science-based inspections and investigations, collect samples for analyses of regulated products, conduct emergency response, consumer complaint follow up, recall activities, and review imported products offered for entry into the United States. Within the field laboratories, FDA performs scientific testing on regulated products in support of inspectional and compliance operations, contributes to applied research, and assists in criminal investigations.

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President’s Budget	(+/-) FY 2026 Enacted
Animal Drugs and Foods	288,353	284,483	281,727	279,317	266,168	-13,149
<i>Budget Authority</i>	230,093	228,574	228,708	218,399	203,219	-15,180
<i>User Fees</i>	58,260	55,909	53,019	60,918	62,949	2,031
FTE	1,066	1,040	1,044	963	985	22

Figure 18 - Animal Drugs and Foods Funding History Table

The FY 2027 Budget for the Animal Drugs and Foods Program is \$266,168,000 including \$203,219,000 in budget authority and \$62,949,000 in user fees. The budget authority decreased by \$15,180,000 and user fees increased by \$2,031,000 compared to the FY 2026 Enacted level.

CVM protects and promotes the health of humans and animals by helping to 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 2027 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 in animals and animal cell- and tissue-based products.
- 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.

CVM will continue supporting the health of food-producing and companion animals, including minor species, and enhance 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 2027 President's Budget: Animal Drugs and Foods	
<i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	218,399
FY 2027 Budget Authority Changes	(15,180)
Operational Imperatives	8,300
MAHA	20,000
Reduction of the Federal Bureaucracy	(43,480)
FY 2027 Budget Net Total: Animal Drugs and Foods	203,219

Figure 19 - Animal Drugs and Foods Budget Authority

Total Budget Authority Changes: -\$15.2 million / 22 FTE

Operational Imperatives: +\$8.3 million / 0 FTE

Protecting User Fee Agreements on Spending and Appropriations Triggers: (+\$8.3 million / 0 FTE)

FDA's request includes \$41.6 million agencywide to protect user fee agreements. This funding is mandatory and required for FDA to be able to continue to collect and spend user fees as required

by statutory mandates. Failure to meet these funding thresholds delay critical program activities and cause significant harm to FDA's operations, stakeholders, and the American public. The Animal Food and Drug Program requests \$8.3 million for this initiative.

MAHA: +\$20.0 million / +22 FTE

Remove Unsafe Chemicals from Food: (+\$20.0 million /+22 FTE)

The FY 2027 Budget provides \$50.0 million across FDA programs to support the Secretary's vision to remove harmful chemicals from the food supply by addressing unsafe chemical additives used in food. It will expand Closer to Zero to eliminate toxic elements from foods consumed by children and develop a compliance system to test naturally derived food colors for elemental contaminants including lead, mercury, arsenic, and cadmium. FDA will invest in addressing food safety gaps, such as developing models to predict levels of PFAS (forever chemicals) in food-producing animals. FDA will also explore legislative solutions to closing the GRAS loophole that allows chemicals with unknown safety data into the food supply. The Animal Food and Drug Program requests \$20.0 million for this initiative.

Reduction to the Federal Bureaucracy: -\$43.5 million / 0 FTE

In line with the administration's efforts to reduce the federal bureaucracy and FDA's FY 2026 President's Budget submission, this budget reflects \$244.8 million of previously accounted reductions across the agency. Previously accounted FTE reductions were reflected in the FY 2026 Enacted Bill.

USER FEES

Current Law User Fees: +\$2.0 million

The Animal Drugs and Foods Program request includes an increase of \$2.0 million for user fees compared to FY 2026 Enacted level.

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 FY 2025, FDA's Animal Drug and Food Program protected human and animal health by:

- Requiring pet food manufacturers to address [H5N1](#) and investigating animal food safety events (for example, *E. Coli* illness in a child linked to [pet food](#)).

- Publishing a model for bioaccumulation of [PFAS](#) (forever chemicals) in cattle and finalized the [AFIC](#) process to facilitate FDA review of ingredient safety.
- Expediting access to [new therapies](#) for pets and food producing animals, including [an indexed](#) broodstock reproduction aid that supports U.S. aquaculture programs.
- Implementing strategies to [Support Antimicrobial Stewardship in Veterinary Settings](#), including testing 7,000+ bacterial isolates for antimicrobial resistance.
- Developing a U.S. strategy, with USDA, to combat the spread of [New World Screwworm](#), a parasitic fly that can infest livestock, pets, and, in rare cases, people.
- FDA’s animal product approval list for [2025](#) is available on its [website](#).
- Increased regulatory harmonization with international partners to increase consistency, reduce barriers for innovation, and increase safety and efficacy of FDA regulated products entering the United States by expanding recognition to six new EU Member States in veterinary medicinal GMP programs. This work saves considerable agency resources while enhancing FDA regulatory oversight and understanding of foreign manufacturers.
- Worked across government to deliver animal food risk management and improve the detection of and mitigation of pathogens, specifically *E. Coli* food borne illness in pet food posing risk to both human and animal safety.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
214221 Percentage of Human and Animal Food significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 98% Target: 65% (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	FY 2025: 76% Target: 50% (Target Exceeded)	50%	50%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
toward compliance. (Outcome)				
224221 Percentage of Human and Animal Drug significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 89% Target: 65% (Target Exceeded)	65%	65%	Maintain
224222 Percentage of Human and Animal Drug follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 44% Target: 40% (Target Exceeded)	40%	40%	Maintain
243231 Complete review and action on non-administrative original New Animal Drug Applications (NADA) and reactivations of such applications received during the fiscal year within 180 days. (Output)	FY 2024: 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 2024: 100% Target: 90% (Target Exceeded)	90%	90%	Maintain
244302 Respond to consumer complaints by initiating in-depth Vet-LIRN investigations within 30 days of receipt. (Output)	FY 2025: 100.0 Target: 90.0 (Target Exceeded)	90%	90%	Maintain

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; 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.

FDA's Devices and Radiological Health Program, including 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 microchip 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. FDA provides consumers, patients, their caregivers, and providers with understandable information about the products it oversees. FDA 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.

FDA's related field activities conduct rigorous, transparent, and science-based inspections and investigations, collect samples for analyses of regulated products, conduct emergency response, consumer complaint follow up, recall activities, and review imported products offered for entry into the United States. Within the field laboratories, FDA performs scientific testing on regulated products in support of inspectional and compliance operations, contributes to applied research, and assists in criminal investigations.

Allocation Methods: Direct Federal/Intramural

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Devices and Radiological Health	746,249	791,300	841,316	913,719	1,005,222	91,503
<i>Budget Authority</i>	449,597	445,593	446,660	454,874	465,974	11,100
<i>User Fees</i>	296,652	345,707	394,656	458,845	539,248	80,403
FTE	2,517	2,540	2,680	2,323	2,330	7

Figure 20 - Devices Funding History Table

The FY 2027 Budget for the Devices Program is \$1,005,222,000 including \$465,974,000 in budget authority and \$539,248,000 in user fees. The budget authority increases by \$11,100,000 and user fees increase by \$80,403,000 when compared to the FY 2026 Enacted level.

FDA's Devices Program assures timely patient access to medical devices that are high-quality, safe, and effective. The FY 2027 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.

The Devices Program focuses on efforts to improve predictability, efficiency, and transparency of FDA regulatory systems so manufacturers can bring novel products to Americans in a timely manner. 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.

BUDGET AUTHORITY

FY 2027 President's Budget: Devices and Radiological Health <i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	454,874
FY 2027 Budget Authority Changes	11,100
Operational Imperatives	9,100
Global Competitiveness and Inspection Capability	2,000
FY 2027 Budget Net Total: Devices and Radiological Health	465,974

Figure 21 - Devices Budget Authority

Total Budget Authority Changes +\$11.1 million / +7 FTE

Operational Imperatives: +9.1 million / 0 FTE

Protect User Fee Agreements: (+\$9.1 million / 0 FTE)

FDA's request includes \$41.6 million agencywide to protect user fee agreements. This funding is mandatory and requires FDA to be able to continue to collect and spend user fees as required by statutory mandates. Failure to meet these funding thresholds delay critical program activities and cause significant harm to FDA's operations, stakeholders, and the American public. The Devices Program requests \$9.1 million for this initiative.

Global Competitiveness/Inspection Capability: +\$2.0 million / +7 FTE

Improving Inspectorate Capabilities: (+\$2.0 million / +7 FTE)

FDA requests \$9.0 million to increase agencywide inspection capacity, safeguard U.S. consumers and patients, and reinforce FDA's global leadership. FDA's inspections and investigations ensure that Americans have timely access to safe and effective food and medical products. Increasing FDA's inspectional capabilities directly supports the Administration's economic priorities as well as the Administration and HHS Secretary's MAHA priorities. Enhancing postmarket surveillance, real-world data, large-scale lifetime interventions with trials, and alternative testing models are all supported and strengthened using FDA's inspectional and investigational activities and are priorities for the Commissioner. The Devices and Radiological Health Program requests 2.0 million for this initiative.

USER FEES

Current Law User Fees: +\$80.4 million

The Devices Program request includes an increase of \$80.4 million for user fees, compared to the FY 2026 Enacted level, which will allow FDA to fulfil its mission of promoting and protecting the public health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM ACCOMPLISHMENTS

There are approximately 248,000 different types of medical devices on the U.S. market, manufactured in more than 24,000 facilities worldwide. 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.

- The Digital Health Center of Excellence advanced digital health by supporting CDRH reviews of medical devices, issuing the [Draft Guidance: Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations](#), convening the Digital Health Advisory Committee to discuss generative AI-enabled digital mental health devices, and announcing the [Technology-](#)

[Enabled Meaningful Patient Outcomes \(TEMPO\) for Digital Health Devices Pilot](#) to continue to promote access to safe digital health technologies.

- In 2025, FDA authorized 46 designated breakthrough devices, including the first blood test to diagnose Alzheimer’s disease and the first eyeglass lenses to slow the progression of pediatric myopia.
- In 2025, FDA added 6 patient organizations to further enable patient collaboration and held a patient engagement townhall on the experience of older adults in medical device clinical studies.
- FDA expanded the Early Alert Pilot to all medical device types to enhance early communication of potentially high-risk device recalls, enabling increased transparency and enhancing patient safety.
- FY 2025 inspections resulted in numerous significant warning letters and included 78 premarket approval inspections and 121 for cause inspections. Successfully initiated unannounced foreign inspection to the device commodity with two conducted in late FY 2025.
- Enhanced the security of the United States surgical field through the completion of intricate regulatory oversight activities producing more than \$40 million in criminal penalties for the sale of adulterated surgical gowns.
- Delivered a more secure medical device supply chain with the refusal and destruction of almost 30,000 medical device units valued at more than \$63,000.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
252223: Percent of total received High Priority MDRs (Code Blue and Death adverse events) reviewed within 10 days during the year. (Output)	FY 2025: 94.7% Target: 90% (Target Exceeded)	90%	90%	Maintain
253207: Number of technical reviews of new applications and data supporting requests for	FY 2024: 2,256 Target: 1,500	1,500	1,500	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
premarket approvals. (Output)	(Target Exceeded)			
253208 Percentage of De Novo requests (petitions to classify novel devices of low to moderate risk) reviewed and classified within 150 days. (Output)	FY 2024: 99% Target: 70% (Target Exceeded)	70%	70%	Maintain
253221 Percentage of Bioresearch Monitoring (BIMO) follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 100% Target: 50% (Target Exceeded)	50%	50%	Maintain
253233 Percentage of received Original PMA, Panel-track PMA Supplement, and Premarket Report Submissions reviewed and decided upon within 180 days. (Outcome) (Outcome)	FY 2024: 98.2% Target: 90% (Target Exceeded)	90%	90%	Maintain
253234 Percentage of 180-day PMA supplements reviewed and decided upon within 180 days. (Outcome)	FY 2024: 99.4% Target: 95% (Target Exceeded)	95%	95%	Maintain
253235 Percentage of 510(k)s (Premarket Notifications) reviewed and decided upon within 90 days (Outcome)	FY 2024: 98.8% Target: 95% (Target Exceeded)	95%	95%	Maintain
254101 Percentage of an estimated 8,900 domestic mammography facilities that meet inspection standards, with less than	FY 2025: 98.9% Target: 97% (Target Exceeded)	97%	97%	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
3% with Level I (serious) problems. (Outcome)				
254203 Percentage of time CDRH meets the targeted deadlines for on-time recall classification (Output)	FY 2025: 99% Target: 85% (Target Exceeded)	85%	85%	Maintain
254221 Percentage of Medical Device and Radiological Health significant inspection violations which receive appropriate follow-up after regulatory action was taken. (Output)	FY 2025: 81% Target: 65% (Target Exceeded)	65%	65%	Maintain
254222 Percentage of Medical Device and Radiological Health follow-up inspections conducted due to regulatory action on significant inspection violations that moved toward compliance. (Outcome)	FY 2025: 64% Target: 50% (Target Exceeded)	50%	50%	Maintain

Figure 22 - Devices and Radiological Health Performance Table

TOBACCO CONTROL ACT

PROGRAM DESCRIPTION

FDA, including 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 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:

- Discouraging people from starting to use tobacco products
- Encouraging people who use tobacco to quit
- Reducing the harm caused by tobacco use

FDA takes a comprehensive approach to reducing the negative health effects of tobacco product use. The agency develops policy, issues regulations, conducts research, educates people on tobacco products, 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. FDA also monitors the tobacco industry for compliance with the law and initiates enforcement actions to protect people from the dangers of tobacco product use.

FDA's related field activities conduct rigorous, transparent, and science-based inspections and investigations, collect samples for analyses of regulated products, conduct emergency response, consumer complaint follow up, recall activities, and review imported products offered for entry into the United States. Within the field laboratories, FDA performs scientific testing on regulated products in support of inspectional and compliance operations, contributes to applied research, and assists in criminal investigations.

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

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Tobacco	677,165	684,760	688,827	688,038	687,120	-918
<i>User Fees</i>	677,165	684,760	688,827	688,038	687,120	-918
FTE	1,303	1,311	1,358	1,124	1,124	---

Figure 23 - CTP Funding History Table

The FY 2027 Budget Request for the Tobacco Program is \$687,120,000 and represents all user fees. This is a decrease of -\$918,000 below the FY 2026 Enacted level.

PROGRAM ACCOMPLISHMENTS

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

- To date, FDA has acted on more than 26 million tobacco product applications. These actions include issuing marketing denial orders (MDOs) for 1.4 million products, of which, over 99% failed to provide evidence of adult benefit for the flavored products compared to tobacco only flavors. FDA also issued marketing granted orders (MGOs) for 87 products, 39 of which are e-cigarette products or devices.
- As a result of authorizations issued in 2025, CTP significantly increased the percentage of e-cigarette products on the U.S. market that are authorized by FDA, and in FY 2025, the Center reduced the backlog of pending PMTAs by 50%, processing applications for over 300,000 products. Among the MGOs FDA issued in 2025, the agency issued its first ever authorizations for nicotine pouch products in January, and pursuant to an innovative pilot program intended to streamline review of nicotine pouch products, the agency then issued an additional six MGOs for such products. The pilot program resulted in FDA completing scientific review in substantially less time than had been performed for other products subject to premarket tobacco applications.
- In CY 2025, FDA conducted over 111,000 retailer inspections, resulting in the issuance of nearly 10,000 warning letters, over 3,800 civil money penalties (CMPs), and 25 no-tobacco-sale orders, which include sales to underage purchasers. Consistent with FDA's priority of enforcing against unauthorized tobacco products, FDA issued over 145 warning letters, 10 CMPs, and 12 injunctions to firms for manufacturing, selling, and/or distributing new tobacco products without marketing authorization; and nearly 100 warning letters and over 55 CMPs to retailers for selling unauthorized products, most of which were products popular with youth.
- FDA initiated a national enforcement effort with its federal partners resulting in the U.S. Department of Justice (DOJ) filing complaints for permanent injunctions in federal district courts against 12 e-cigarette manufacturers, distributors, and retailers on behalf of FDA, alone resulted in the seizure of over 6.5 million units of unauthorized ENDS

products valued at well over \$100 million, with nearly all products seized and destroyed originating from China.

- FDA launched an initiative to increase voluntary compliance from retailers about which tobacco products are legal to sell, mailing informational materials to more than 300,000 retailers nationwide. Also in 2025, FDA’s “The Real Cost” youth e-cigarette prevention campaign won two prestigious Effie awards in the Disease Awareness & Education - Non-Profit/Health & Wellness and Youth Marketing - Services categories. A [new study](#) found that “The Real Cost” campaign contributed to the nearly 70% decline in e-cigarette use among American youth that has occurred since 2019, and prevented nearly 450,000 youth from starting e-cigarette use over a one-year period.
- FDA’s Searchable Tobacco Products Database is available on its [website](#).
- Completed numerous focused activities in FY 2025 including the successful completion of targeted ENDS joint operations with Customs and Border Protection (CBP) resulting in the seizure of almost 7 million unauthorized e-cigarettes valued at more than \$120 million and executing a historic first tobacco seizure with the DOJ worth approximately \$700 million.
- Made significant advancements of tobacco compliance protocols and detention tools for imported products to improve efficiency of enforcement activities and prevent unauthorized products from reaching Americans.
- Full inspections data by product type and interactive dashboard can be found on this website: [FDA Dashboards - Inspections](#)

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 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
280005 Total number of tobacco compliance check inspections of retail establishments in States under contract. (Intermediate Outcome)	FY 2025: 118,980 Target: 70,000 (Target Exceeded)	80,000	80,000	Maintain
280010 Number of closed applications and deficiency letters for Premarket Tobacco Product Applications (PMTA). (Output)	FY 2025: 356,916 Target: 700 (Target Exceeded)	700	700	Maintain

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2026 Target	FY 2027 Target	FY 2027 Target +/-FY 2026 Target
280011 Number of closed applications and deficiency letters for Substantial Equivalence (SE) Reports. (Output)	FY 2025: 1,166 Target: 600 (Target Exceeded)	600	600	Maintain
280012 Number of closed applications and deficiency letters for Exemption from Substantial Equivalence Requests (EX REQ). (Output)	FY 2025: 800 Target: 290 (Target Exceeded)	300	300	Maintain
280037 Percentage of youth (12-17 years old) reached with campaign messages about the harmful effects of tobacco use. (Output)	FY 2025: 80% Target:75% (Target Exceeded)	75.	70%	-5

Figure 24 - Tobacco Control Act Performance Table

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

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 historically conducted over 100,000 inspections each fiscal year, except during the COVID-19 pandemic. In FY 2026 and FY 2027, 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.

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 administrative letters such as withdrawal. 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 2026 and FY 2027 targets have been reduced. However, as FDA authorizes ENDS under the PMTA program, the EX REQ-pathway becomes available to ENDS manufacturers that are limited to an additive modification of the tobacco product and thus may increase the number of submissions under this pathway for FY 2026 and FY 2027.

Educate At-Risk Youth 12-17 Year Olds

FDA's public education campaigns educate the public, especially youth, about the dangers of regulated tobacco products to protect the public's health. Due to growing Center-wide resource constraints, FDA has had to make difficult resource trade-offs and reallocate funding away from our education programs to support other priorities. Therefore, we anticipate the target will decrease to 70 percent in FY 2027.

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 agencywide 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 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Office of the Commissioner	362,323	382,849	364,043	345,073	302,900	-42,173
<i>Budget Authority</i>	222,940	241,304	234,981	219,852	171,569	-48,283
<i>User Fees</i>	139,383	141,545	129,062	125,221	131,331	6,110
FTE	963	1,005	1,056	1,000	1,008	8

Figure 25 – FDA OC's Funding History Table

The FY 2027 Budget for OC is \$302,900,000 including \$171,569,000 in budget authority and \$131,331,000 in user fees. The budget authority decreases by \$48,283,000 and user fees increase by \$6,110,000 compared to the FY 2026 Enacted level.

BUDGET AUTHORITY

FY 2027 President's Budget: Office of the Commissioner	
<i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	219,852
FY 2027 Budget Authority Changes	(48,283)
MAHA	12,000
Global Competitiveness and Inspection Capability	2,470
Reduction of the Federal Bureaucracy	(62,753)
FY 2027 Budget Net Total: Office of the Commissioner	171,569

Figure 26 – FDA OC's Budget Authority

Total Budget Authority Changes: -\$48.3 million / +8 FTE

MAHA: \$12.0 million / +3 FTE

Removing Unsafe Chemicals from Food: (\$5.0 million/ +3 FTE)

The FY 2027 Budget provides \$50.0 million across FDA programs to support the Secretary’s vision to remove harmful chemicals from the food supply by addressing unsafe chemical additives used in food. It will expand Closer to Zero to eliminate toxic elements from foods consumed by children and develop a compliance system to test naturally derived food colors for elemental contaminants including lead, mercury, arsenic, and cadmium. FDA also requires funding to invest in addressing food safety gaps, such as developing models to predict levels of PFAS in food-producing animals. The initiative will explore ways legislative can be used to close the GRAS loophole. The Office of the Commissioner requests \$5.0 million for this initiative.

Artificial Intelligence and Machine Learning: (\$2.0 million/ 0 FTE)

To improve FDA’s centralized process systems for pediatric knowledge management and drugs designated for rare diseases using artificial intelligence (AI) and machine learning (ML), the agency requests +\$2.0 million. These systems require modernization and enhancements, including enhancements with AI, to support cross-Center collaboration to improve agency efficiency.

Alternatives to Animal Testing: (\$5.0 million/ 0 FTE)

FDA requires \$5.0 million to support crosscutting intra- and extramural regulatory science research and development to advance the development and use of alternatives to animal testing (new approach methodologies, or NAMs) to support the agency’s regulatory decision making.

Global Competitiveness & Inspection Capabilities: \$2.5 million / +5 FTE

Foreign Office Expansion: (\$2.5 million/ +5 FTE)

FDA requests \$2.5 million to strengthen FDA's oversight of imported products by expanding the agency's foreign office footprint. The proposed expansion includes opening a new office in Asia which performs food and medical product inspections. This approach strengthens the Department's foreign presence and supports global health security and pandemic preparedness initiatives.

Reduction to the Federal Bureaucracy: -\$62.8 million / 0 FTE

In line with the administration's efforts to reduce the federal bureaucracy and FDA's FY 2026 President's budget submission, this budget reflects \$244.8 million of previously accounted reductions across the agency.

USER FEES

Current Law User Fees: +\$6.1 million

The FY 2027 Budget includes an increase of \$6.1 million in current law user fees for OC. The remaining resources will allow FDA to fulfill its mission of promoting and protecting human and animal health by ensuring safety and efficacy of FDA-regulated products.

PROGRAM ACCOMPLISHMENTS

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

- Issued 16 vouchers under the Commissioner's National Priority Review Voucher pilot program to products with the potential to address one or more key national priorities.
- Modernized agency functions by consolidating fragmented adverse event databases, releasing adverse event reports in real time, and launching an internal AI tool to help FDA employees work more efficiently.
- Restored public trust in the agency through actions such as publishing FDA rejection letters, addressing conflicts of interest on FDA advisory committees, and cracking down on falsified Chinese testing data.
- Supported the Office of the United States Trade Representative in the development of text in more than 30 reciprocal trade agreements to advance the Administration's America First trade policy and level the playing field for American manufacturers of FDA regulated commodities.
- The Oncology Center of Excellence approved 10 [Real-Time Oncology Review \(RTOR\)](#) applications. RTOR enables more efficient reviews by providing FDA reviewers earlier data access, identifying data quality issues, and facilitating early applicant feedback. The program allows submission of topline efficacy and safety results before the complete application, supporting earlier FDA evaluation to ensure safe and effective treatments reach patients sooner while maintaining review quality.
- In support of the FDA foods, medical products, and tobacco programs, FDA has completed more than 14,600 domestic inspections, more than 2,600 foreign inspections,

more than 159,600 examinations of products offered for import into the United States during FY 2025.

- In FY 2025, OCI investigated significant criminal violations and disrupted those who pose a risk to public health, resulting in 117 arrests, 129 convictions, and more than \$340 million in forfeiture, fines, and restitution.

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 Target +/-FY 2025 Target
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. (Output)	FY 2025: 92 Target: 70 (Target Exceeded)	70	70	Maintain
291406 Percentage of invoices issued on time within predefined dates in the month. (Output and Efficiency)	FY 2025: 100% Target: 98% (Target Exceeded)	98%	98%	Maintain
293205 Percentage of requests for combination product designations processed within the 60-day statutory requirement. (Output)	FY 2025: 100% Target: 95% (Target Exceeded)	95%	95%	Maintain
214206 Maintain accreditation for OII labs. (Outcome)	FY 2025: 12 labs Target: 12 labs (Target Met)	12 labs	12 labs	Maintain
292201 Improve FDA's ability to respond quickly and efficiently to crises and emergencies that	FY 2025 Results: Developed 107 mapping products in support of FDA’s emergency preparedness, response, and	Develop 60 mapping products in support of	Develop 60 mapping products in support of	N/A

Measure	Year and Most Recent Result / Target for Recent Result / (Summary of Result)	FY 2025 Target	FY 2026 Target	FY 2026 Target +/-FY 2025 Target
involve FDA regulated products. (Output)	<p>recovery activities. Participated in six exercises during the year.</p> <p>Target: Develop 60 mapping products in support of FDA’s emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.</p> <p>(Target Not Met)</p>	<p>FDA’s emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.</p>	<p>FDA’s emergency preparedness, response, and recovery activities. Participate in seven exercises during the year.</p>	

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

Crises and Emergency Response Measures

In FY 2025, FDA participated in six emergency, preparedness, response, and recovery exercises to improve FDA’s ability to respond quickly and efficiently to crises and emergencies that involve FDA regulated products. FDA missed the goal by one exercise due to several factors and will strive to meet the target of seven exercises moving forward.

INFRASTRUCTURE – GSA RENT, OTHER RENT, AND WHITE OAK

PROGRAM DESCRIPTION

FDA’s Infrastructure Program supports the agency’s laboratory, inspectional, investigative, and office facilities nationwide. The program covers General Services Administration (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.

The Infrastructure Program consists of:

- GSA Rental Payments
- Other Rent and Rent Related Activities (OR&RR)
- White Oak

Infrastructure investments advance strategic Administration priorities and is crucial to empower FDA's workforce to make America healthy again.

Allocation Methods: Direct Federal/Contract

BUDGET REQUEST

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
FDA White Oak Campus	56,293	55,061	54,917	44,400	44,400	---
<i>Budget Authority</i>	48,414	52,498	52,498	41,998	41,998	---
<i>User Fees</i>	7,879	2,563	2,419	2,402	2,402	---
Other Rent and Rent Related	164,550	161,165	160,259	161,366	161,326	-40
<i>Budget Authority</i>	106,095	154,879	154,879	154,879	154,848	-31
<i>User Fees</i>	58,455	6,286	5,380	6,487	6,478	-9
GSA Rental Payments	244,884	228,038	212,288	209,023	212,937	3,914
<i>Budget Authority</i>	166,286	163,000	155,000	144,935	146,363	1,428
<i>User Fees</i>	78,598	65,038	57,288	64,088	66,574	2,486

Figure 27 – Infrastructure Funding History Table

The FY 2027 Budget for the Infrastructure Program includes a total of \$343,209,000 in budget authority, an increase of \$1,397,000 from the FY 2026 Enacted level; and \$75,454,000 in user fees, an increase of \$2,477,000 above the FY 2026 Enacted level.

The increase 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. This increase reflects GSA's standard annual rent escalations and adjustments in occupancy costs across FDA's facilities portfolio. The additional funding ensures continued occupancy of critical facilities that support FDA's regulatory mission and operations.

The Infrastructure Program supports FDA’s offices and laboratories 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 2027 Budget for the Infrastructure Program includes the following budget authority:

FY 2027 President's Budget:	
Infrastructure	
<i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	341,812
FDA White Oak Campus	41,998
Other Rent and Rent Related	154,879
GSA Rental Payments	144,935
FY 2027 Budget Authority Changes	59,933
Operational Imperatives	59,933
FDA White Oak Campus	-
Other Rent and Rent Related	46,433
GSA Rental Payments	13,500
Reduction of the Federal Bureaucracy	(58,536)
Other Rent and Rent Related	(46,464)
GSA Rental Payments	(12,072)
FY 2027 Budget Net Total: Infrastructure	343,209
FDA White Oak Campus	41,998
Other Rent and Rent Related	154,848
GSA Rental Payments	146,363

Figure 28 – Infrastructure Budget Authority

Total Budget Authority Changes: +\$1.4 million**Other Rent and Rent-Related: –\$31,000**

The FY 2027 Budget for Other Rent and Rent Related (OR&R) includes a total of \$154.8 million in budget authority, a decrease of \$31,000 below the FY 2026 Enacted level.

The OR&R program covers essential operational costs not included in GSA rental payments, including utilities, maintenance contracts, security services, and equipment repairs at FDA-owned and GSA-controlled facilities nationwide. This funding ensures functional laboratories and offices that support FDA's regulatory mission by maintaining safe, secure work environments. The slight decrease reflects operational efficiencies and cost management initiatives while preserving critical infrastructure services. Without adequate OR&R funding, vital operations including research activities, inspections, and emergency response capabilities would be compromised, potentially disrupting FDA's ability to protect public health.

GSA Rental Payments: +\$1.4 million

The FY 2027 Budget for the GSA Rental Payments includes a total of \$146.4 million, an increase of \$1.4 million above the FY 2026 Enacted level.

This increase supports FDA's continued occupancy of approximately 6.5 million square feet across 246 GSA-controlled locations nationwide, reflecting standard annual rent escalations and market rate adjustments. These facilities house critical laboratories, district offices, and field operations essential for FDA's inspection, investigation, and regulatory activities. The funding ensures uninterrupted access to strategically located facilities that enable FDA scientists and regulators to conduct essential research, product reviews, and field operations. Adequate GSA rental funding is crucial for maintaining FDA's nationwide presence and operational capacity to protect public health.

USER FEES**Current Law User Fees: +\$2.5 million**

OR&R: –\$12,000

GSA Rent: +\$2.5 million

The Infrastructure Program request includes a total increase of \$2.5 million in user fees when compared to the FY 2026 Enacted level.

WHITE OAK UPDATE

The FY 2027 request for White Oak is \$44.4 million, of which \$42.0 million is budget authority and \$2.4 million is user fees. The funding is necessary to provide above GSA-standard repairs and improvements as well as critical White Oak Campus utility infrastructure capacity and reliability improvements required to prevent facilities from degrading and assure that they remain state of the-art to support ever evolving science. It also provides funding needed for daily mission support services for employees and visitors on the White Oak Campus, including, transportation services, labor and loading dock services, and a centralized safety program. Furthermore, this request ensures that FDA has the necessary resources to move forward with

consolidating five headquarters-area GSA-leases onto to the Campus as part of a consolidation that, when complete in 2029, will reduce FDA’s real estate footprint by approximately 597,000 square feet and avoid \$31.9 million in annual rent and security costs.

PROGRAM ACCOMPLISHMENTS

The Infrastructure Program directly supports Administration priorities by providing safe, secure, modern, and cost-effective laboratory, inspectional, investigative, and office space. These empower FDA’s workforce to protect public health, accelerate cures, ensure healthier food for children, unleash the power of artificial intelligence and big data, and efficiently make benefit risk calculations. 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 GSA-controlled and FDA-owned sites nationwide, ensuring regulatory program continuity.
- Initiating a headquarters consolidation that will reduce FDA’s real property footprint by approximately 597,000 square feet by the end of 2029. Coordinating leasing and 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 the agency’s presence in seven International Mail Facilities, to enhance opioid interdiction efforts and 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 laboratory standards. B&F investments are vital to sustaining scientific and regulatory operations and safeguarding mission-critical functions across FDA.

The B&F program’s 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, protects the federal investment in its facilities, and empowers FDA employees to make America healthy again.

Allocation Methods: Direct Federal/Contract

(Dollars in Thousands)	FY 2023 Final	FY 2024 Final	FY 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	(+/-) FY 2026 Enacted
Buildings and Facilities (Budget Authority)	12,788	5,000	5,000	5,000	5,000	---

Figure 29 – Buildings and Facilities Funding History

BUDGET REQUEST

FY 2027 President's Budget: Buildings and Facilities <i>Budget Authority - Dollars in Thousands</i>	
	Total
FY 2026 Enacted:	5,000
FY 2027 Budget Authority Changes	-
FY 2027 Budget Net Total: B&F	5,000

Figure 30 – Budget Authority

The FY 2027 Budget for B&F includes \$5,000,000 in budget authority, flat with the FY 2026 Enacted level.

The B&F Program’s funding is essential to maintain, repair, and improve FDA’s owned facilities, which primarily house laboratories. This funding will enable FDA to modernize outdated infrastructure, address critical maintenance needs, and ensure compliance with safety and laboratory standards at mission-critical owned facilities. The B&F investments will enhance

operational continuity, improve laboratory functionality for scientific experimentation, strengthen emergency preparedness capabilities, and create more reliable work environments. These improvements will empower FDA's workforce to effectively evaluate and regulate medical, food, and tobacco products while supporting the agency's public health mission.

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, negatively 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 protect public health, accelerate cures, ensure healthier food for children, unleash the power of artificial intelligence and big data, and efficiently make benefit-risk calculations.

FDA must support its 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 2027, FDA plans to initiate the following projects, pending the availability of funding.

Gulf Coast Seafood Laboratory - Dauphin Island, Alabama

- No projects scheduled.

Muirkirk Road Complex (MRC) - Laurel, Maryland

FDA will initiate facility improvement projects to:

- Replace clean steam generator serving the campus.
- Replace hot water tanks in MOD2.

Pacific Southwest Laboratory - Irvine, California

- Initiate a study and design to upgrade generator capacity on campus.

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 2027 funds.

FY 2027 BUILDINGS AND FACILITIES ALLOCATION PLAN

FY 2027 Buildings and Facilities Allocation Plan	
Site	FY 2027 Budget
Gulf Coast Seafood Laboratory – Dauphin Island, AL	\$0
Muirkirk Road Complex (MOD1, MOD2, BRF) – Laurel, MD	\$4,500,000
Pacific Laboratory SW – Irvine, CA	\$500,000

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 31 – Buildings and Facilities Allocation Plan

In FY 2027, the condition of FDA-owned real property assets and site infrastructure remains 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 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.

Program accomplishments include the following:

- Continued developing a land-use feasibility study for four acres of land newly transferred from the U.S. Coast Guard on Dauphin Island, AL, to allow FDA to relocate laboratory operations from its aged and functionally obsolete, existing, nearby Gulf Coast Seafood Laboratory to a newly constructed modern, safe, reliable, laboratory building.
- Replaced aged transformers and vacuum switches at the Muirkirk Road Complex.
- Upgraded the LAN Room cooling system at the Pacific Southwest Lab.

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 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	FY 2027 PB +/- FY 2026 Enacted
<u>Personnel Compensation and Benefits:</u>				
Personnel Compensation:				
Full-time permanent (11.1).....	1,156,636	1,079,746	1,093,808	14,062
Other than full-time permanent (11.3).....	101,583	94,830	96,065	1,235
Other personnel compensation (11.5).....	43,304	40,425	40,951	526
Military Personnel - Basic Allowance for Housing (11.6)	75	77	80	3
Military personnel (11.7).....	82,028	85,145	88,210	3,065
Special personnel services payments (11.8).....	424	396	401	5
Subtotal, Personnel Compensation.....	1,384,049	1,300,619	1,319,515	18,896
Benefits:				
Civilian benefits (12.1).....	476,682	444,994	450,789	5,795
Military benefits (12.2).....	8,430	8,750	9,065	315
Benefits to former personnel (13.0).....	23,746	22,167	22,456	289
Subtotal, Benefits.....	508,858	475,911	482,310	6,399
Total Personnel Compensation and Benefits.....	1,892,907	1,776,530	1,801,825	25,295
<u>Contractual Services and Supplies</u>				
Contractual Services:				
Travel and transportation of persons (21.0).....	28,601	28,255	26,786	-1,469
Transportation of things (22.0).....	2,605	2,573	2,439	-134
Rental payments to GSA (23.1).....	155,000	144,935	146,363	1,428
Rent payments to others (23.2).....	1,022	1,010	957	-53
Communication, utilities, and misc. charges (23.3).....	13,092	12,934	12,261	-672
Printing and reproduction (24.0).....	256	253	240	-13
Subtotal, Contractual Services.....	200,577	189,960	189,047	-913
Other Contractual Services:				
Consulting services (25.1).....	51,638	51,012	48,360	-2,652
Other services (25.2).....	349,738	345,503	327,539	-17,964
Purchase of goods and svcs from Govt Acts. (25.3).....	541,246	534,692	506,892	-27,800
Operation and maintenance of facilities (25.4).....	95,374	94,219	89,321	-4,899
Research and Development Contracts (25.5).....	15,632	15,443	14,640	-803
Medical care (25.6).....	16,052	15,857	15,033	-824
Operation and maintenance of equipment (25.7).....	87,780	86,717	82,209	-4,509
Subtotal, Other Contractual Services.....	1,157,459	1,143,444	1,083,993	-59,450
Supplies and Materials:				
Supplies and materials (26.0).....	29,786	29,426	27,896	-1,530
Equipment (31.0).....	9,650	9,533	9,037	-496
Land and Structures (32.0).....	35,388	34,959	33,142	-1,818
Grants, subsidies, and contributions (41.0).....	172,615	170,525	161,659	-8,866
Insurance claims and indemnities (42.0).....	876	866	821	-45
Interest and dividends , Refunds (43.0, 44.0).....	---	---	---	---
Receivables-collected (61.7).....	---	---	---	---
Confidential expenditures (91.0).....	152	150	142	-8
Subtotal, Supplies and Materials.....	248,467	245,459	232,697	-12,762
Total Contractual Services and Supplies.....	1,606,503	1,578,862	1,505,737	-73,125
Total Budget Authority by Object Class.....	3,499,410	3,355,392	3,307,562	-47,830

Figure 32 – 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 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	FY 2027 PB +/- FY 2026 Enacted
<u>Personnel Compensation and Benefits:</u>				
Personnel Compensation:				
Full-time permanent (11.1).....	1,349,059	1,148,608	1,148,608	---
Other than full-time permanent (11.3).....	138,125	117,602	117,602	---
Other personnel compensation (11.5).....	68,219	58,082	58,082	---
Military Personnel - Basic Allowance for Housing (11.6).....	51	53	55	2
Military personnel (11.7).....	80,262	83,312	86,312	2,999
Special personnel services payments (11.8).....	246	209	209	---
Subtotal, Personnel Compensation.....	1,635,962	1,407,867	1,410,868	3,001
Benefits:				
Civilian benefits (12.1).....	545,591	464,524	464,524	---
Military benefits (12.2).....	11,046	11,466	11,879	413
Benefits to former personnel (13.0).....	20,201	17,199	17,199	---
Subtotal, Benefits.....	576,839	493,190	493,603	413
Total Personnel Compensation and Benefits.....	2,212,801	1,901,057	1,904,471	3,414
<u>Contractual Services and Supplies</u>				
Contractual Services:				
Travel and transportation of persons (21.0).....	12,022	17,062	19,852	2,791
Transportation of things (22.0).....	1,043	1,480	1,722	242
Rental payments to GSA (23.1).....	57,288	64,088	66,574	2,486
Rent payments to others (23.2).....	694	986	1,147	161
Communication, utilities, and misc. charges (23.3).....	122	172	201	28
Printing and reproduction (24.0).....	30	43	50	7
Subtotal, Contractual Services	71,199	83,831	89,546	5,715
Other Contractual Services:				
Consulting services (25.1).....	107,414	152,446	177,382	24,936
Other services (25.2).....	369,173	523,944	609,647	85,702
Purchase of goods and svcs from Govt Acts. (25.3).....	506,554	718,921	836,516	117,595
Operation and maintenance of facilities (25.4).....	5,017	7,120	8,285	1,165
Research and Development Contracts (25.5).....	11,824	16,781	19,526	2,745
Medical Care (25.6).....	15,332	21,760	25,319	3,559
Operation and maintenance of equipment (25.7).....	65,611	93,118	108,350	15,232
Subtotal, Other Contractual Services.....	1,080,926	1,534,091	1,785,025	250,934
Supplies and Materials:				
Supplies and materials (26.0).....	2,653	3,765	4,381	616
Equipment (31.0).....	1,210	1,717	1,998	281
Land and Structures (32.0)	2,545	3,613	4,203	591
Grants, subsidies, and contributions (41.0).....	79,776	113,221	131,741	18,520
Insurance claims and indemnities (42.0).....	5	8	9	1
Interest and dividends , Refunds (43.0, 44.0).....	23,286	33,048	38,454	5,406
Receivables-collected (61.7).....	---	---	---	---
Confidential expenditures (91.0).....	18	26	30	4
Subtotal, Supplies and Materials.....	109,494	155,398	180,817	25,419
Total Contractual Services and Supplies.....	1,261,618	1,773,320	2,055,388	282,068
Total User Fees by Object Class.....	3,474,419	3,674,376	3,959,858	285,482
Total User Fees by Object Class, Less Refunds (44.0).....	3,451,133	3,641,328	3,921,404	280,076

Figure 33 – 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 2025 Final	FY 2026 Enacted	FY 2027 President's Budget	FY 2027 PB +/- FY 2026 Enacted
<u>Personnel Compensation and Benefits:</u>				
Personnel Compensation:				
Full-time permanent (11.1).....	2,505,695	2,228,354	2,242,416	14,062
Other than full-time permanent (11.3).....	239,708	212,432	213,667	1,235
Other personnel compensation (11.5).....	111,522	98,507	99,034	526
Military Personnel - Basic Allowance for Housing (11.6).....	125	130	135	5
Military personnel (11.7).....	162,290	168,457	174,521	6,064
Special personnel services payments (11.8).....	670	605	610	5
Subtotal, Personnel Compensation.....	3,020,011	2,708,486	2,730,383	21,897
Benefits:				
Civilian benefits (12.1).....	1,022,274	909,518	915,313	5,795
Military benefits (12.2).....	19,476	20,216	20,944	728
Benefits to former personnel (13.0).....	43,947	39,367	39,655	289
Subtotal, Benefits.....	1,085,697	969,101	975,913	6,812
Total Personnel Compensation and Benefits.....	4,105,708	3,677,587	3,706,296	28,709
<u>Contractual Services and Supplies</u>				
Contractual Services:				
Travel and transportation of persons (21.0).....	40,623	45,317	46,638	1,322
Transportation of things (22.0).....	3,647	4,053	4,161	108
Rental payments to GSA (23.1).....	212,288	209,023	212,937	3,914
Rent payments to others (23.2).....	1,717	1,995	2,104	109
Communication, utilities, and misc. charges (23.3).....	13,214	13,106	12,462	-644
Printing and reproduction (24.0).....	286	296	290	-6
Subtotal, Contractual Services.....	271,775	273,790	278,593	4,802
Other Contractual Services:				
Consulting services (25.1).....	159,052	203,458	225,742	22,284
Other services (25.2).....	718,911	869,447	937,186	67,739
Purchase of goods and svcs from Govt Acts. (25.3).....	1,047,800	1,253,613	1,343,408	89,795
Operation and maintenance of facilities (25.4).....	100,391	101,340	97,606	-3,734
Research and Development Contracts (25.5).....	27,456	32,224	34,166	1,942
Medical care (25.6).....	31,384	37,617	40,352	2,735
Operation and maintenance of equipment (25.7).....	153,392	179,835	190,558	10,723
Subtotal, Other Contractual Services.....	2,238,385	2,677,535	2,869,019	191,484
Supplies and Materials:				
Supplies and materials (26.0).....	32,439	33,191	32,276	-914
Equipment (31.0).....	10,860	11,250	11,035	-215
Land and Structures (32.0).....	37,933	38,572	37,345	-1,227
Grants, subsidies, and contributions (41.0).....	252,391	283,746	293,400	9,654
Insurance claims and indemnities (42.0).....	882	873	830	-44
Interest and dividends , Refunds (43.0, 44.0).....	23,286	33,048	38,454	5,406
Receivables-collected (61.7).....	---	---	---	---
Confidential expenditures (91.0).....	170	176	172	-4
Subtotal, Supplies and Materials.....	357,961	400,856	413,513	12,657
Total Contractual Services and Supplies.....	2,868,122	3,352,182	3,561,124	208,943
Total Program Level by Object Class.....	6,973,829	7,029,768	7,267,420	237,652
Total Program Level by Object Class, Less Refunds (44.0).....	6,950,543	6,996,720	7,228,966	232,246

Figure 34 – Total Program Level by Object Class

DETAIL OF FULL-TIME EQUIVALENTS

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

	FY 2025 Actuals			FY 2026 Enacted			FY 2027 President's Budget		
	Civilian	Military	Total	Civilian	Military	Total	Civilian	Military	Total
Human Foods Program.....	1,546	53	1,599	1,841	53	1,894	1,873	53	1,926
Center for Drug Evaluation and Research	5,690	404	6,094	5,409	404	5,813	5,428	404	5,832
Center for Biologics Evaluation and Research	1,430	55	1,485	1,244	55	1,299	1,244	55	1,299
Center for Veterinary Medicine	707	14	721	692	14	706	714	14	728
Center for Devices and Radiological Health	2,149	55	2,204	1,805	56	1,861	1,805	56	1,861
National Center for Toxicological Research	-	-	-	-	-	-	-	-	-
Center for Tobacco Products.....	1,230	47	1,277	987	47	1,034	987	47	1,034
Headquarters and Office of the Commissioner.....	956	43	999	957	43	1,000	965	43	1,008
Office of Investigations and Inspections	3,137	223	3,360	3,831	260	4,091	3,867	260	4,127
Field Laboratory Operations.....	683	49	732	177	12	189	177	12	189
Color Certification	20	-	20	37	-	37	37	-	37
Export Certification	33	2	35	24	2	26	24	2	26
Priority Review Vouchers (PRV) Tropical Disease.....	1	0	1	-	-	-	-	-	-
Priority Review Vouchers (PRV) Pediatric Disease	22	0	22	11	0	11	11	0	11
Priority Review Vouchers (PRV) Medical Countermeasures.....	-	-	-	-	-	-	-	-	-
Over the Counter Monograph (OMUFA).....	67	3	70	93	3	96	93	3	96
Opioids - No Year.....	-	-	-	-	-	-	-	-	-
21st Century Cures (BA Only).....	73	1	74	-	-	-	-	-	-
Cancer Moonshot (BA Only).....	-	-	-	-	-	-	-	-	-
Total.....	17,743	950	18,693	17,107	950	18,057	17,224	950	18,174

* FTE figures do not include an estimated 38 reimbursable, 1 FOIA, 19 PEPFAR, and 36 HCFAC.

**FY 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2025 and FY 2026 FTE levels are displayed comparably and as a result does not include 287 FTE in FY 2025 and 199 FTE in FY 2026 for this program.

Figure 35 – Detail of Full-Time Equivalents

DETAIL OF POSITIONS

**Food and Drug Administration
Detail of Positions**

	FY 2025 Final	FY 2026 Enacted	FY 2027 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.....	\$218,513	\$220,698	\$220,698
Executive Service (ES)			
Executive Service.....	26	26	23
Total Executive Service.....	26	26	23
Total - ES Salary.....	\$5,746,314	\$5,803,777	\$5,164,422
General Schedule (GS)			
GS-15.....	605	493	539
GS-14.....	3,232	2,631	2,876
GS-13.....	5,214	4,245	4,640
GS-12.....	2,168	1,765	1,929
GS-11.....	496	403	441
GS-10.....	5	4	5
GS-9.....	214	174	190
GS-8.....	12	10	11
GS-7.....	131	106	116
GS-6.....	8	6	7
GS-5.....	7	5	6
GS-4.....	1	1	1
GS-3.....	3	2	2
GS-2.....	1	1	1
GS-1.....	---	---	---
Total General Schedule.....	12,097	9,848	10,764
Total - GS Salary.....	\$1,657,763,233	\$1,363,055,876	\$1,489,917,703
Administrative Law Judges (AL).....	---	---	---
Scientific/Senior Level (ST/SL).....	---	---	---
Senior Biomedical Research Service (RS).....	46	46	41
Scientific Staff Fellows (RG) (Title 42).....	876	876	779
Distinguished Consultants/Senior Science Managers (RF) (Title 42) ..	57	57	51
Former Performance Mgmt Recognition System Employees (GM)	---	---	---
Physicians and Dentists - (GP) (Title 38)	182	182	162
Commissioned Corps (CC):			
Commissioned Corps - 08/07/06.....	194	194	194
Commissioned Corps - Other	756	756	756
Total Commissioned Corps.....	950	950	950
Administratively Determined (AD) (includes Title 42) ²	4,639	4,639	4,128
Wage Grade	7	7	6
Consultants ²	1,425	1,425	1,268
Total FTE (End of Year)¹.....	20,306	18,057	18,174
Average ES Level	1	1	1
Average ES Salary	\$218,513	\$220,698	\$220,698
Average GS grade	13	13	13
Average GS Salary	\$137,040	\$138,410	\$138,410
Average GM Salary	---	\$0	\$0
Average GP Salary	\$239,707	\$242,104	\$242,104

¹ Does not include 38 reimbursable, 1 FOIA, 19 PEPFAR, and 36 HCFAC.
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 2027 Budget reorganizes the National Center for Toxicological Research (NCTR) from FDA to CDC. The FY 2025 and FY 2026 FTE levels are displayed comparably and as a result does not include 287 FTE in FY 2025 and 199 FTE in FY 2026 for this program.

Figure 36 - Detail of Positions

FDA SPECIFIC ITEMS

GEOGRAPHICAL DISTRIBUTION OF FDA FACILITIES

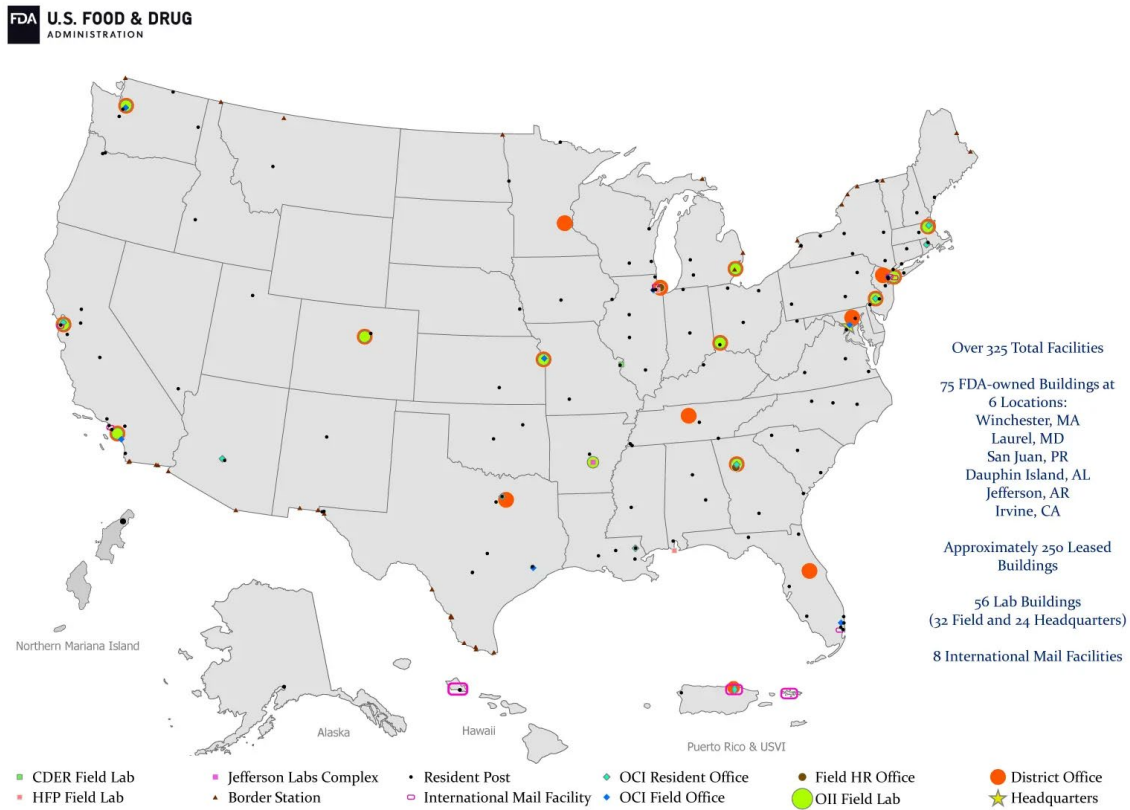


Figure 37 – Geographic Distribution of FDA Facilities

The disposition of the Jefferson Labs Complex in Jefferson, Arkansas – until FY 2027, the home to FDA's National Center for Toxicological Research (NCTR) – may be subject to change due to NCTR's realignment from FDA to the Centers for Disease Control and Prevention (CDC)

FDA CENTRAL ACCOUNTS

Food and Drug Administration FDA Central Account				
Program (dollars in thousands)	FY 2025 Actuals		FY 2026 Estimates	
	BA	UF	BA	UF
Foods.....	19,633	-	19,566	-
Center.....	10,699	-	9,592	-
Field.....	5,939	-	6,964	-
Field Lab Operations.....	2,995	-	3,011	-
Human Drugs.....	15,147	41,658	13,727	44,324
Center.....	9,829	40,231	8,076	42,313
Field.....	4,089	1,427	4,355	2,011
Field Lab Operations.....	1,228	-	1,296	-
Biologics	6,264	8,142	6,286	9,225
Center.....	4,418	8,073	4,304	9,135
Field.....	1,838	69	1,973	90
Field Lab Operations.....	08	-	08	-
Animal Drugs and Feeds.....	5,196	1,458	5,332	1,536
Center	3,261	1,458	3,166	1,536
Field.....	1,700	-	1,940	-
Field Lab Operations.....	235	-	227	-
Devices and Radiological Health.....	12,011	10,357	10,602	11,642
Center.....	8,516	10,213	6,982	11,461
Field.....	3,206	143	3,315	181
Field Lab Operations.....	289	-	305	-
National Center for Toxicological Research.....	1,855	-	2,126	-
Family Smoking Prevention and Tobacco Control Act.....	-	9,868	-	10,206
Center.....	-	9,432	-	9,493
Field.....	-	209	-	330
Field Lab Operations.....	-	227	-	383
FDA Headquarters	4,715	5,218	4,627	4,622
Total.....	64,820	76,700	62,266	81,556

Figure 38 – FDA Central Accounts

DRUG CONTROL

Budget Authority (in millions)			
	FY 2025	FY 2026	FY 2027
	Final	Enacted	President's Budget
Drug Resources by Budget Decision Unit and Function			
Center for Drug Evaluation and Research			
Research and Development: Prevention	\$6.45	\$6.45	\$6.45
Harm Reduction	\$10.00	\$10.00	\$10.00
Research and Development: Treatment	\$7.05	\$7.05	\$7.05
Center for Device and Radiological Health			
Research and Development: Prevention	\$1.00	\$1.00	\$1.00
Research and Development: Treatment	\$0.50	\$0.50	\$0.50
Office of Inspections and Investigations			
Interdiction	\$42.29	\$42.29	\$42.29
Office of the Chief Scientist			
Interdiction	\$11.71	\$11.71	\$11.71
Office of Operations			
Interdiction	\$0.50	\$0.50	\$0.50
Total Drug Resources by Function	\$79.50	\$79.50	\$79.50
Drug Resources by Decision Unit			
Center for Drug Evaluation and Research	\$23.50	\$23.50	\$23.50
Center for Devices and Radiological Health	\$1.50	\$1.50	\$1.50
Office of Inspections and Investigations	\$42.29	\$42.29	\$42.29
Office of the Chief Scientist	\$11.71	\$11.71	\$11.71
Office of Operations	\$0.50	\$0.50	\$0.50
Total Drug Resources by Decision Unit	\$79.50	\$79.50	\$79.50
Drug Resources Personnel Summary			
Total FTEs (direct only)	196	196	196
Drug Resources as a Percent of Budget			

Figure 39 – FDA Drug Control Budget Authority

Program Summary

Mission

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

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

FDA also recognizes the risks of prescription opioids and other controlled substances as well as the benefits of these drugs for patients who need them, including those with debilitating chronic conditions. It will take carefully developed, coordinated, and sustained action by multiple stakeholders to reduce the incidence of drug misuse, abuse, addiction, overdose, and death, while preserving appropriate access to these drugs for patients who need them. Doing our part to ensure the safe use of prescription opioids and other controlled substances and ameliorate the overdose crisis is among FDA's highest priorities.

The FY 2027 drug control budget aligns to the HHS planned reorganization, which will save taxpayer dollars and streamline the functions of the Department in order to end our country's chronic illness epidemic. Additionally, it aligns with the Office of National Drug Control Policy's April 2025 Statement of Drug Policy Priorities.

Methodology

FDA identified the drug control budget by using the dedicated budget authority for activities involving prescription opioids and other controlled substances. This includes opioids dedicated base activities conducted by the Center for Drug Evaluation and Research (CDER), the Center for Devices and Radiological Health (CDRH), the Office of Inspections and Investigations (OII), the Office of the Chief Scientist (OCS) and the Office of Operations (OO).

Budget Summary

The FY 2027 Budget at the flat level is \$79.5 million for drug control program activities at FDA.

Center for Drug Evaluation and Research (CDER)

President's Budget: \$23.5 million

The FY 2027 Budget for drug-related activities includes \$23.5 million for CDER to further develop and advance strategies to confront the opioid crisis. CDER is committed to supporting research that addresses questions that are critical to our work on the overdose crisis. CDER

utilizes the \$23.5 million in opioids base funding to further develop and implement evidence-based actions to address FDA's priority areas.

Some of CDER's recent research initiatives include:

- Advancing the development of multiple evidence-based clinical practice guidelines on management of acute dental pain, management of post-operative pain in obstetric patients who have undergone surgery, management of post-operative pain in patients who have undergone laparoscopic abdominal surgeries, management of acute low back pain, and safe tapering of benzodiazepines; the first four guidelines are part of SUPPORT Act Sec. 3002 implementation.
- Supporting the development and regulatory assessment of new and generic opioid overdose reversal agents, including naloxone, and exploring strategies to optimize the use of approved opioid overdose reversal agents.
- Conducting a kratom human abuse potential study, including assessment of safety, pharmacokinetic, and pharmacodynamic characteristics.
- Exploring the scope of use, potential safety risks, and access issues regarding racemic ketamine for emerging therapeutic areas, such as mental health disorders and pain.
- Exploring efforts to accelerate treatment development for post-traumatic stress disorder, including psychedelic drug development.
- Examining the transitions from medical use of prescription stimulants and opioids to risks such as nonmedical use, illicit drug use, and substance use disorders.

FDA-supported research initiatives have enhanced our understanding of appropriate use of prescription opioids for pain treatment, as well as risks and mitigating factors to address opioid misuse, abuse, overdose, and death. However, the high rates of fatal overdose involving synthetic opioids, other substances with abuse potential, polysubstance use, and the enduring impact of the COVID-19 pandemic indicate further work is needed to address the overdose crisis.

Center for Devices and Radiological Health (CDRH)

President's Budget: \$1.5 million

The FY 2027 Budget for opioid-related activities includes \$1.5 million for CDRH to continue supporting the use of digital health medical devices to help address opioid use disorder (OUD).

CDRH continues to encourage the development of new and innovative medical devices to broaden the number of options and increase the effectiveness of OUD treatment through recent research initiatives that include:

- Completing a patient preference study for people living with OUD, including a literature review, focus groups, and a quantitative study. The results are in peer review for publication.
- Using funds to collaborate with the Research Triangle Center for Excellence in Regulatory Science for a project aimed at determining how sensor-based DHTs can be used to assess for risk of relapse in OUD. This work continued through FY 2025 with a completed patient survey and systematic review of relapse determinants in OUD, the latter of which is being considered for publication. Continuing collaboration with the Research Triangle Center for Excellence in Regulatory Science on a project aimed at

determining how sensor-based digital health technologies can be used to assess for risk of relapse in OUD.

- Conducting a systematic review of relapse determinants in OUD and preparing the manuscript for submission.
- Research, engagement, and partnership with academic and community medical centers and others for development of digital health technologies for OUD.
- Leveraging real-world data to inform medical device regulatory decision making by improving premarket assessment.
- Leveraging post-market surveillance data of devices used to assess, monitor, treat and manage OUD.

Going forward, CDRH will build upon these efforts by using the funds to:

- Leverage real world data to support novel, digitally derived endpoint development and pilot the use of real-world performance to further understand how digital health technologies can support the effective treatment of OUD.
- Continue research, engagement, and partnership with academic medical centers and others for the development of digital health technologies for OUD.
- Use data gathered on patient preferences to help inform clinical trial design and assist in fostering shared decision-making for clinicians treating people living with OUD.

Office of Inspections and Investigations (OII) – Field Activities

President’s Budget: \$42.29 million

In response to the current opioid crisis, OII continues to combat illicit opioids that are illegally marketed unapproved opioids and support innovation in medical devices that help to combat the opioid crisis through multipronged approaches. OII’s Office of Import Operations (OIO) and Office of Criminal Investigations (OCI) protect the public health by monitoring FDA-regulated products shipped into the nation’s eight international mail facilities (IMFs) and courier hubs to prevent unsafe, counterfeit, and unapproved drugs from entering the United States. Our continued partnership with U.S. Customs and Border Protection (CBP) and the United States Postal Service (USPS) enables onsite examination of parcels that appear to contain drug products. While CBP leads the interception of illegally imported controlled substances, Office of Import Operations (OIO) staff, with support from the Office of the Chief Scientist (OCS) play a crucial role in removing unapproved, adulterated, misbranded, or otherwise impermissible drug products from the U.S. market.

In FY 2025, OII staff reviewed more than 111,000 products entering the United States via international mail and refused admission of over 72,000 drug products. Those refusals resulted in more than 14.8 million pieces/tablets/capsules of unapproved drugs, including opioids, from entering the United States, with more than 12.6 million of those being destroyed by OII. As a result of these activities, active pharmaceutical ingredients (APIs) have been recommended to be added to the list for administrative destruction under section 801(u) of the Act. OII also continues to complete focused sample collections to support the surveillance of the quality of the pharmaceutical supply chain. The opioid quality assignments are intended to survey the pharmaceutical supply chain (e.g., manufacturers of drugs and drug products, including

repackagers) of opioid products, as well as opioid agonists and antagonists (opioid products) to identify potential quality risks or economically motivated adulteration in the supply chain.

OII's response to the opioid crisis extends beyond regulatory actions and includes criminal enforcement against those who fuel the opioid crisis. OII's OCI partners with the Department of Justice to investigate and prosecute individuals and entities who contribute the opioid crisis through illegal marketing, false claims, and other criminal conduct. OCI's investigations have led to significant accountability for major corporate actors. In FY 2025, McKinsey & Company—a global management consulting firm—entered into a 5-year deferred prosecution agreement and agreed to pay \$650 million for its role in helping Purdue Pharma “turbocharge” the sales of the highly addictive opioid OxyContin during a period when deadly overdoses were surging nationwide.

Furthermore, OCI targets individuals and networks selling counterfeit drugs, such as fentanyl analogues and benzodiazepines, on the web and social media platforms as well as the online infrastructure that supports and facilitates such illegal sales. These internet investigative efforts have produced demonstrable results: over the last five years, through the end of FY 2025, OCI's internet investigative efforts have resulted in 129 arrests, 97 convictions, as well as the seizure of over \$41 million in financial assets and drug counterfeiting paraphernalia. OCI also takes strong action against medical professionals who betray their position of trust and tamper with opioids intended for patients. In 2025, an OCI investigation led to the sentencing of a nurse to more than five years in federal prison for tampering with fentanyl intended for patients at five different hospitals in the Tampa Bay area.

Additional advancements include enhanced collaborations with USPS via an MOU resulted in data integration which allowed the USPS and FDA to develop an electronic international mail data exchange system tailored for parcels processed at IMFs. This exchange system promises heightened productivity and targeting capacity and supports our efforts to combat illicit and illegal drug importation. FDA and USPS jointly implemented this bilateral interface to exchange postal data more effectively for examined parcels.

Since the inception of the National Operational Strategy, FDA import staff (in collaboration with CBP) have conducted forty-two operations that successfully intercepted over 1,025,000 tablets and capsules of unapproved drugs (including opioids) from entering U.S. commerce. In conjunction with this work, FDA import staff have intercepted 1,041 products that have been referred to CBP for enforcement follow-up.

Office of the Chief Scientist (OCS)

President's Budget: \$11.71 million

FDA's Forensic Chemistry Center became the National Chemistry Center (NFCC) in the Office of Specialty Laboratories and Enforcement Support (OSLES) in FY 2025. This realignment increased scientific collaborations both within and outside of FDA, ultimately increasing the agency's scientific capabilities and capacity to protect public health. The NFCC supports criminal and regulatory investigations of suspect counterfeit pharmaceuticals and tampered medications. Case submissions in FY 2024 include treatments for anxiety, diabetes, weight loss, and pain

management, including opioid drugs, as well as many others. Use of some of these products have a high risk of dependency and others do not have any approved use in the United States.

Scientists from the NFCC are working with counterparts from CBP's Laboratories and Scientific Services (LSS) and Drug Enforcement Agency's (DEA) Special Testing Laboratory to establish a program that generates chemical attribution information or chemical fingerprints of counterfeit and illicit opioid tablets and other emerging hazardous illicit drugs. This agreement between the three organizations has been formally expressed in a Memorandum of Understanding. The current program called INTREPID (Intelligence National Threat Response- El Paso Illicit Drug) enables laboratories from the three agencies to share and leverage vast technical knowledge and intelligence from their different areas of expertise. The data derived from INTREPID offers investigators and the intelligence community in-depth analysis of seized materials to identify trafficking linkages and geo-sourcing of illicit drugs and precursor materials. The two current high priority INTREPID projects include analysis and comparison of seized counterfeit tablets containing fentanyl, seized fentanyl powders, and the analysis of xylazine. To date, NFCC has received 64 samples of seized tablets from CBP containing fentanyl and fentanyl powders and are in the process of being analyzed. Results generated by NFCC analyses are being shared and combined with the results generated by CBP and DEA. NFCC, CBP and DEA scientists meet bi-weekly to discuss on going sample analysis, share data on samples analyzed and share information on new emerging illicit drug threats. Eventually, the INTREPID program will be based at EPIC (El Paso Intelligence Center, Ft. Bliss), where scientists from each of the three agencies will be co-located, eliminating the need to split and ship evidence. Planning for the renovation space and build out of the laboratory at EPIC is in progress.

In FY 2024, Satellite Laboratories opened in New York and Los Angeles, and the Honolulu Satellite Lab opened in FY2025. Since inception, NFCC satellite laboratories have examined more than 4,000 products. Over 90 percent of these potentially dangerous products, consisting of over 1.9 million lot units, were destroyed or refused entry into the United States, with 1,606 products and nearly 900,000 lot units destroyed or refused entry in FY2025 alone.

OCS's Office of Analytical and Regulatory Laboratories (OARL) includes four medical product testing laboratories that routinely perform surveillance testing of controlled substances to assess the manufacturing quality. These products are targeted through directed assignments from the Center for Drug Evaluation and Research (CDER) and/or the [Drug Quality Sampling and Testing Programs](#) (DQST). OARL also supports inspections of human drug manufacturing facilities, including those that produce controlled substances, by providing chemists and microbiologists who possess both scientific subject matter expertise and training in agency inspectional policies and procedures. The four testing laboratories work closely with FDA components to support the [Medication Health Fraud](#) program which screens products for illegal drugs and unapproved pharmaceuticals.

Office of Operations (OO)**President's Budget: \$0.5 million**

FDA/OII's Division of Information Disclosure Policy (DIDP) relocated to the OO with the FY 2024 reorganization. The Division of Freedom of Information (DFOI) also relocated to the OO. DFOI manages the intake, triaging, and appeals for all FDA FOI requests, including those related to opioids and drug control. With continued FDA involvement, regulation, and media attention in an opioid-related commodities and products, FOIA and other information disclosure workloads will grow in the opioid and drug control area. An MOU involving analysis of opioids in a joint research collaboration and information sharing agreement with CBP and DEA may also require DIDP redaction resources. In addition, special redaction projects, including litigation and information sharing requests from state, federal, and foreign partner regulatory agencies, in the drug area continue to be initiated.

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