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The Food and Drug Administration (FDA) Budget: Fact Sheet

Updated June 10, 2026

Congressional Research Service
https://crsreports.congress.gov
R44576

CRS REPORT
Prepared for Members and
Committees of Congress

Summary

The Food and Drug Administration (FDA) regulates the safety of foods (including dietary supplements), cosmetics, and radiation-emitting products; the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices; and the public health aspects of tobacco products. FDA is organized into various offices and centers that carry out the agency's regulatory responsibilities. The Office of the Commissioner and six other program area centers oversee the core functions of the agency. These include the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), the Center for Tobacco Products (CTP), the Center for Veterinary Medicine, and the Human Foods Program. In addition, FDA has numerous offices, including the Office of Inspections and Investigations (OII), the Office of Operations, the Office of the Chief Scientist, the Office of External Affairs, and the Office of Women's Health, among others. The National Center for Toxicological Research (NCTR) is housed within the Office of the Chief Scientist.

FDA's *total program level*, the amount that FDA can spend, comprises discretionary appropriations from two different sources: annual appropriations (i.e., discretionary budget authority, or BA) and user fees paid by the regulated industry (e.g., drug manufacturers). In FDA's annual appropriation, Congress sets both the total amount of appropriated funds and the amount of user fees that the agency is authorized to collect and obligate for that fiscal year.

Between FY2021 and FY2026, FDA's enacted annual *total program level* (excluding amounts enacted in supplemental appropriations measures or in the American Rescue Plan Act [P.L. 117-2]) increased from $6.050 billion to $7.069 billion. Over that time period, congressionally appropriated funding increased by about 2%, while user fee revenue increased by more than 30%. The Administration's FY2027 request for a *total program level* of $7.227 billion would be an increase of more than $160 million (+2%) over the FY2026-enacted amount.

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FDA Overview

The Food and Drug Administration (FDA) regulates the safety of foods (including dietary supplements), cosmetics, and radiation-emitting products; the safety and effectiveness of drugs, biologics (e.g., vaccines), and medical devices; and public health aspects of tobacco products.[1] Although FDA has been a part of the Department of Health and Human Services (HHS) since 1940, the Committees on Appropriations do not consider funding for FDA with most of the rest of HHS under their Subcommittees on Labor, Health and Human Services, and Education, and Related Agencies. Jurisdiction over FDA's budget remains with the Subcommittees on Agriculture, Rural Development, Food and Drug Administration, and Related Agencies, reflecting FDA's beginning as part of the Department of Agriculture.

FDA's organization consists of various offices and centers that carry out the agency's regulatory responsibilities. The Office of the Commissioner and six other program area centers oversee the core functions of the agency. These include the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), the Center for Tobacco Products (CTP), the Center for Veterinary Medicine, and the Human Foods Program. In addition, FDA has numerous offices, including the Office of Inspections and Investigations (OII),[2] the Office of Operations, the Office of the Chief Scientist, the Office of External Affairs, and the Office of Women's Health, among others.[3] The National Center for Toxicological Research (NCTR) is housed within the Office of the Chief Scientist.

The agency's budget—as presented in the Justifications of Estimates for Appropriations Committees (referred to as *Congressional Justifications*, or CJs) and the materials of the Committees on Appropriations—is organized by program area. Consistent with these budget documents, **Table 1** displays funding for FY2021 through FY2026, as well as the FDA's FY2027 request, by program area (e.g., Human Foods, Human Drugs).

Funding Sources

FDA's *total program level*, the amount that FDA can spend, is composed of discretionary appropriations from two different sources. First, FDA is appropriated funding out of the Treasury's General Fund. (This is the usual source of funding for discretionary appropriations, and, in keeping with the conventions used in FDA budget documents, is referred to in this report as *budget authority*.)[4] Second, FDA also is allowed to collect and obligate *user fees*.[5] FDA's

[1] Several CRS reports have information on FDA authority and activities: CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*, and CRS Report R47374, *FDA Regulation of Medical Devices*.

[2] The Office of Inspections and Investigations (OII) is FDA's sole regulatory field operations organization and is responsible for field inspection, investigation, import, emergency response, and law enforcement activities. For more information on OII, see FDA, Office of Inspections and Investigations, at https://www.fda.gov/about-fda/fda-organization/office-inspections-and-investigations.

[3] FDA Organization, https://www.fda.gov/media/190947/download?attachment, accessed May 27, 2026.

[4] In its technical sense, the term *budget authority* refers to the authority to enter into obligations, and *appropriations* are a form of budget authority. However, in keeping with the convention used by the FDA budget justifications, this section of the report uses this term only to refer to the General Fund appropriations, and not the funding that comes from the user fees collected by the agency. For further information, see CRS Report R44582, *Overview of Funding Mechanisms in the Federal Budget Process, and Selected Examples*.

[5] Beginning with enactment of the Prescription Drug User Fee Act (PDUFA, P.L. 102-571) in 1992, FDA has been authorized to collect fees from industry sponsors of certain FDA-regulated products and to use the proceeds to support statutorily defined activities, such as the review of product marketing applications. Several CRS reports describe FDA (continued...)

annual appropriation sets both the amount of budget authority and the amount of user fees that the agency is authorized to collect and obligate for that fiscal year. The budget authority appropriations are largely for the Salaries and Expenses account, with a smaller amount for the Buildings and Facilities account, the latter of which is used for any changes to, or purchases of, fixed equipment and facilities used by FDA.[6] The appropriations of the several different user fees contribute only to the Salaries and Expenses account.

For each of the FDA user fee programs, the authorizing legislation establishes the legal framework that governs the fees, while the annual appropriations acts provide FDA the authority to collect and expend them. The largest and oldest FDA user fee that is linked to a specific program was first authorized by the Prescription Drug User Fee Act (PDUFA; P.L. 102-571) in 1992. PDUFA sets the total amount of user fee revenue for the first year, provides a formula for annual adjustments, and includes limiting conditions to ensure that user fees supplement congressional appropriations (i.e., General Fund appropriations) rather than replace them. After PDUFA, Congress added other user fee authorities, for example, regarding medical devices, biosimilar biologics. animal drugs, generic drugs, tobacco products, and other FDA-regulated products and activities. Generally, the medical product user fees have been authorized in legislation on a five-year cycle.[7] Each five-year authorization sets a total amount of fee revenue for the first year and provides a formula for annual adjustments to that total based on inflation and other adjustments. In contrast, the nonmedical product user fee programs do not require reauthorization and are generally indefinite. **Table A-1** presents the list of user fees that contribute to FDA's budget, sorted by the dollar amount they contribute to the agency's FY2027 budget request. The table also includes the authorizing legislation for each current user fee, specifies whether the user fee program requires reauthorization, and provides the most recent reauthorization, if applicable.

The 21st Century Cures Act (Cures Act; P.L. 114-255), signed into law in December 2016, made several changes to the drug and device approval pathways at FDA to support innovation and accelerate development and review of certain medical products (e.g., combination products, antimicrobials, drugs for rare disease, and regenerative therapies). To fund these activities, the Cures Act established an FDA Innovation Account to which a total of $500 million was authorized to be transferred over a nine-year period (FY2017-FY2025).[8] The law specified that amounts in the account were not available until appropriated in subsequent appropriations acts and that once made available, these amounts are available until expended. The amounts subsequently appropriated (i.e., the budget authority and the resulting outlays) for FY2017 through FY2025, up to the amounts transferred, were to be subtracted from any cost estimates provided for purposes of budget controls. Effectively, the appropriations from the account would not be counted against any spending limits, such as the statutory discretionary spending limits; that is, the amounts appropriated from the account would be considered outside those limits for FY2017 through FY2025.

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user fee programs. See, for example, CRS Report R44750, *FDA Human Medical Product User Fee Programs*, and CRS In Focus IF12821, *Over-The-Counter Monograph Drug User Fee Program (OMUFA) Reauthorization*.

[6] In FY2026, the Buildings and Facilities account made up $5 million of the agency's $3.427 billion enacted budget authority. See **Table 1** for further detail.

[7] The medical product user fee programs that are authorized together are PDUFA, the Medical Device User Fee Act (MDUFA), the Generic Drug User Fee Amendments (GDUFA), and the Biosimilar User Fee Act (BsUFA). In addition, the Animal Drug User Fee Act (ADUFA) and the Animal Generic Drug User Fee Act (AGDUFA) are also authorized on a separate five-year cycle, as is the Over-the-Counter (OTC) Monograph User Fee Program (OMUFA).

[8] For each of FY2017 through FY2025, the following amounts are authorized to be transferred to the FDA Innovation Account: $20 million in FY2017, $60 million in FY2018, $70 million in FY2019, $75 million in FY2020, $70 million in FY2021, $50 million in FY2022, $50 million in FY2023, $50 million in FY2024, and $55 million in FY2025.

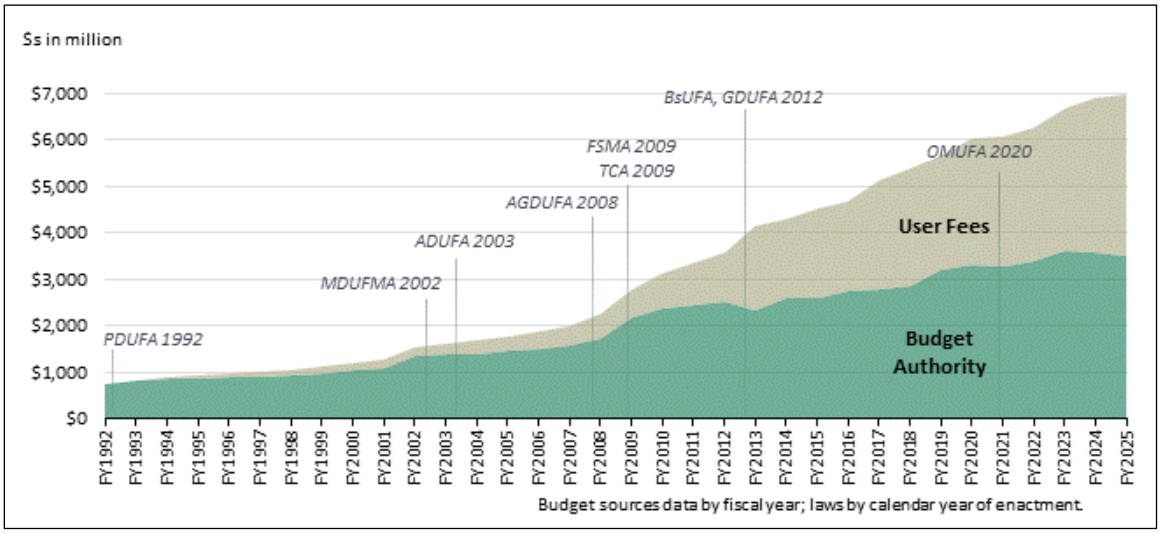
In general, this report focuses on funding provided as part of the regular appropriations process. As such, this report does not include in the total amounts emergency funding provided in supplemental appropriations acts; these supplemental amounts are noted, where applicable, in the **Table 1** notes. Given the historical significance of the COVID-19 pandemic and the provision of additional funding in FY2020 and FY2021 for FDA to respond to the pandemic, this report includes a summary of this funding in **Appendix B**.

FDA Funding History and FY2026 Appropriations

Since the enactment of PDUFA in 1992, FDA's spending from user fees has generally increased, both in absolute terms and as a share of FDA's total budget, accounting for nearly 50% of the agency's FY2025 total program level (see **Figure 1**).

Figure 1. FDA Spending, by Source, FY1992-FY2025

(in millions of dollars)



Source: Figure created by CRS using the FY1992 through FY2027 FDA CJs.

Notes: These amounts have not been adjusted for inflation. The purpose of this figure is to show how FDA's spending has changed over time to include a greater proportion from user fees compared to budget authority. The amounts used in this figure are from the "Actual" columns in the FDA CJs, with the exception of FY2021-FY2025, which reflect "Final" columns. Beginning with the FY2021 CJ, the FDA began using the term "final" to refer to certain prior-year numbers. Earlier FDA CJs used the term "actual" when referring to such numbers. This report follows the FDA wording convention in the applicable source document. PDUFA = Prescription Drug User Fee Act; MDUFMA = Medical Device User Fee and Modernization Act; ADUFA = Animal Drug User Fee Act; AGDUFA = Animal Generic Drug User Fee Act; TCA = The Family Smoking Prevention and Tobacco Control Act; FSMA = Food Safety Modernization Act; BsUFA = Biosimilar User Fee Act; GDUFA = Generic Drug User Fee Amendments; OMUFA = Over-the-Counter Monograph User Fee Act.

Between FY2021 and FY2026, FDA's enacted annual *total program level* (excluding amounts enacted in supplemental appropriations measures or in the American Rescue Plan Act)[9] increased from $6.050 billion to $7.069 billion (see **Table 1**). Over that time period, congressionally appropriated funding increased by 7%, while user fee revenue increased by more than 39%. The

[9] Coronavirus Disease 2019 (COVID-19)-related supplemental appropriations and the FDA-related provisions in the American Rescue Plan Act of 2021 (P.L. 117-2) are discussed in **Appendix B**.

FY2026-enacted appropriation provides $3.428 billion in *budget authority* as well as an additional $3.641 billion in *user fees*.

The Administration's FY2027 request for a *total program level* of $7.158 billion would be an increase of $89 million (+7%) over the FY2026-enacted amount. The FY2027 request proposes $3.308 billion in *budget authority*—a decrease of $119 million (-3%) from the FY2026-enacted amount.[10] **Table 1** includes FDA Innovation Account money in the total budget authority and program level amounts for FY2021 through FY2026, consistent with the budget display conventions used in the FDA CJs.

The FY2027 budget request proposes $3.850 billion in user fees—an increase of about $209 million (+6%) over the FY2026-enacted amount—to be collected through authorized programs to support specified agency activities regarding prescription drugs, over-the-counter drugs, medical devices, animal drugs, animal generic drugs, tobacco products, generic human drugs, biosimilars, mammography quality, color certification, export certification, food reinspection, food recall, the voluntary qualified importer program, outsourcing facilities, priority review vouchers, and third-party auditors. In addition to the $3.850 billion in user fees from currently authorized programs, the FY2027 request includes an additional $71 million in *unauthorized* user fees, which would come from a proposed new foreign food facility registration fee.[11]

It is estimated that including the proposed fees would bring the FDA's total requested user fee amount to $3.921 billion.

Consistent with the Administration's and congressional budget display conventions, **Table 1** displays, by program area, the budget authority (direct appropriations), user fees (excluding proposed, unauthorized fees), and total program levels for FDA from FY2021 through FY2026 and the FY2027 request. The human drugs program comprises the largest portion of FDA's budget (35% in FY2026), followed by the human foods program (17% in FY2026), and the devices and radiological health program (13% in FY2026).

Table 1. Food and Drug Administration (FDA) Appropriations

(in millions of dollars)

Program Area	FY2021 Final	FY2022 Final	FY2023 Final	FY2024 Final	FY2025 Final	FY2026 Enacted	FY2027 Request
Human Foods	**1,110**	**1,145**	**1,208**	**1,183**	**1,192**	**1,185**	**1,293**
BA	1,099	1,133	1,196	1,171	1,179	1,171	1,280
Fees	11	12	12	12	13	13	13
Human drugs	**1,997**	**2,116**	**2,284**	**2,338**	**2,429**	**2,498**	**2,537**
BA	689	714	761	720	724	685	632
Fees	1,308	1,402	1,522	1,619	1,704	1,813	1,905
Biologics	**437**	**457**	**491**	**572**	**607**	**601**	**574**

[10] The Administration's FY2027 request proposes moving the functions of the National Center for Toxicological Research to a new National Center for Chemicals and Toxins housed in the Centers for Disease Control and Prevention (CDC). The $119 million decrease is in part a reflection of this proposal. If NCTR's budget authority for FY2026 is omitted from that year's total, then FY2027's request is $47 million less than the amount enacted for FY2026.

[11] The FY2027 FDA CJ includes a legislative proposal to amend Section 415 of the FFDCA to establish a biennial registration fee for all foreign human and animal food facilities; FDA is not currently authorized to collect such fees. For more information on this proposal, see FY2027 FDA CJ, p. 20, at https://www.fda.gov/media/191778/download?attachment#page=22.

Program Area	FY2021 Final	FY2022 Final	FY2023 Final	FY2024 Final	FY2025 Final	FY2026 Enacted	FY2027 Request
BA	254	260	272	268	268	259	207
Fees	183	197	218	304	339	342	367
Animal drugs and foods	**245**	**255**	**288**	**284**	**282**	**279**	**266**
BA	192	202	230	229	229	218	203
Fees	53	53	58	56	53	61	63
Devices and radiological health	**628**	**648**	**746**	**791**	**841**	**914**	**1,005**
BA	408	420	450	446	447	455	466
Fees	220	228	297	346	395	459	539
Tobacco products	**682**	**680**	**677**	**685**	**689**	**688**	**687**
Fees	682	680	677	685	689	688	687
Toxicological research	**67**	**70**	**77**	**78**	**78**	**72**	[a]
BA	67	70	77	78	78	72	
Headquarters/ Commissioner's Office	**320**	**331**	**362**	**383**	**364**	**345**	**303**
BA[b]	195	206	223	241	235	220	172
Fees	125	125	139	142	129	125	131
GSA rent	**236**	**237**	**245**	**228**	**212**	**209**	**213**
BA	167	166	166	163	155	145	146
Fees	69	70	79	65	57	64	67
Other rent, rent-related activities[c]	**189**	**193**	**221**	**216**	**215**	**206**	**206**
BA	130	133	155	207	207	197	197
Fees	59	60	66	9	8	9	9
Over the Counter Monograph[d]	**28**	**25**	**30**	**32**	**36**	**38**	**40**
Fees	28	25	30	32	36	38	40
Export, color certification	**15**	**16**	**16**	**16**	**16**	**16**	**16**
Fees	15	16	16	16	16	16	16
Priority review voucher	**13**	**13**	**14**	**14**	**12**	**13**	**13**
Fees	13	14	14	14	12	13	13
FDA Innovation Account	**70**	**50**	**50**	**50**	**50**	**0**	**0**
BA	70	50	50	50	50	0	0
Buildings & Facilities[e]	**13**	**13**	**13**	**5**	**5**	**5**	**5**

Program Area	FY2021 Final	FY2022 Final	FY2023 Final	FY2024 Final	FY2025 Final	FY2026 Enacted	FY2027 Request
BA	13	13	13	5	5	5	0
Total Budget Authority	**3,285**	**3,367**	**3,593**	**3,577**	**3,577**	**3,427**[a]	**3,308**
Total User Fees	**2,766**	**2,881**	**3,129**	**3,298**	**3,451**	**3,641**	**3,850**[f]
Total Program Level	**6,050**[g]	**6,248**	**6,722**	**6,876**	**7,029**	**7,069**[a]	**7,158**

Sources: The FY2023-FY2027 FDA CJs; the Consolidated Appropriations Act, 2021 (P.L. 116-260); the Consolidated Appropriations Act, 2022 (P.L. 117-103); the Consolidated Appropriations Act, 2024 (P.L. 118-42); the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs and Extensions Act, 2026 (P.L. 119-37); and the accompanying explanatory statements.

Notes: BA = budget authority. Individual amounts may not add to subtotals or totals due to rounding. Marginal changes in line items year-to-year may not be reflected due to rounding.

a. The FY2027 President's budget proposes a new National Center for Chemicals and Toxins housed in the CDC that would include NCTR as well as the National Center for Environmental Health, National Institute for Occupational Safety and Health, the Administration for Toxic Substance Research, and the National Institute of Environmental Health Sciences. As such, the Total Budget Authority and Total Program Level indicated in this table for FY2026 do not align with those values as presented in the All-Purpose Table in the FY2027 FDA CJ. For more information on the proposal, see FY2027 CDC CJ at https://www.cdc.gov/budget/documents/fy2027/fy-2027-cdc-cj.pdf.

b. These amounts do not reflect the transfer of $1.5 million to the HHS Office of Inspector General for FDA oversight required in the enacted appropriation for those years.

c. Other rent and rent-related activities include FDA White Oak Campus consolidation.

d. The Over-the-Counter Monograph User Fee Amendments, most recently reauthorized through FY2030 by the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026, authorizes FDA to assess and collect fees for certain OTC drug activities. The FY2027 CJ does not show how this money is distributed and in what amounts across programs (e.g., human drugs, headquarters).

e. This total does not include the $20 million provided by Section 780 of P.L. 116-94 for the Buildings and Facilities account, which is "to remain available until expended and in addition to amounts otherwise made available for such purposes, for necessary expenses of plans, construction, repair, improvement, extension, alteration, demolition and purchase of fixed equipment or facilities of or used by FDA for seafood safety."

f. This amount reflects only those user fees that have been authorized in legislation when the FY2027 budget request was issued. Keeping in convention with previous iterations of this report, the amount listed in the table does not include proposed user fees that have not been authorized by Congress. FDA's FY2027 request proposes an additional $71 million in unauthorized user fees via a new foreign food facility and registration fee. Including the proposed fees would bring the FDA's total requested user fee amount to $3.921 billion. The indefinite fees are distributed by program area consistent with the FY2026 Enacted column in the All-Purpose Table in the FY2027 FDA Justification of Estimates for Appropriations Committees.

g. This total does not include supplemental appropriations provided to FDA to remain available until expended "to prevent, prepare for, and respond to coronavirus" or the $500 million provided to the Secretary by the American Rescue Plan Act of 2021 (ARPA; P.L. 117-2) for medical countermeasure activities at FDA. The total also does not include the $1 million provided by Section 765 of P.L. 116-260 "to remain available until expended and in addition to amounts otherwise made available for such purposes, for the development of research, education, and outreach partnerships with academic institutions to study and promote seafood safety."

Appendix A. FDA User Fee Authorizations and Anticipated Collections

Table A-1. FDA User Fee Authorizations and Anticipated Collections

(in order of FY2027 anticipated collections)

User Fee	Initial Authorizing Legislation and Year	Most Recent Reauthorization and Year, and Length of Current Authorization	FY2027 Anticipated Collections (in millions of dollars)
Prescription drug	Prescription Drug User Fee Act (PDUFA; P.L. 102-300), 1992	Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (P.L. 117-180), 2022 FY2023-FY2027	1,640
Tobacco product	Family Smoking Prevention and Tobacco Control Act (TCA; P.L. 111-31), 2009	Does not require reauthorization	712
Generic drug	Food and Drug Administration Safety and Innovation Act (FDASIA; P.L. 112-144), 2012	Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (P.L. 117-180), 2022 FY2023-FY2027	704
Medical device	Medical Device User Fee and Modernization Act (MDUFMA; P.L. 107-250), 2002	Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (P.L. 117-180), 2022 FY2023-FY2027	560
Biosimilar	Food and Drug Administration Safety and Innovation Act (FDASIA; P.L. 112-144), 2012	Continuing Appropriations and Ukraine Supplemental Appropriations Act, 2023 (P.L. 117-180), 2022 FY2023-FY2027	62
Over the Counter Monograph	The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), 2020	Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (P.L. 119-37) FY2026-FY2030	40
Animal drug	Animal Drug User Fee Act (ADUFA; P.L. 108-130), 2003	Continuing Appropriations Act, 2024 and Other Extensions Act (P.L. 118-15), 2023 FY2024-2028	36
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA; P.L. 110-316), 2008	Continuing Appropriations Act, 2024 and Other Extensions Act (P.L. 118-15), 2023 FY2024-2028	29

User Fee	Initial Authorizing Legislation and Year	Most Recent Reauthorization and Year, and Length of Current Authorization	FY2027 Anticipated Collections (in millions of dollars)
Mammography	Mammography Quality Standards Act (MQSA; P.L. P.L. 102-539), 1992	Does not require reauthorization	20
Color certification	Color Additive Amendments (P.L. 86-618), 1960	Does not require reauthorization	11
Rare pediatric disease priority review voucher	Food and Drug Administration Safety and Innovation Act (FDASIA; P.L. 112-144), 2012[a]	Does not require reauthorization	10
Food reinspection	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	8
Voluntary qualified importer program (VQIP)	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	7
Export certification	FDA Export Reform and Enhancement Act (P.L. 104-134), 1996 [for medical products]; Food Safety Modernization Act (FSMA; P.L. 111-353), 2011 [for foods]	Does not require reauthorization	5
Tropical disease priority review voucher	Food and Drug Administration Amendments Act (FDAAA; P.L. 110-85), 2007	Does not require reauthorization	3
Outsourcing facility	Drug Quality and Security Act (DQSA; P.L. 113-54), 2013[b]	Does not require reauthorization	2
Food and feed recall	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	2
Third party auditor program	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	1
Medical counter-measures priority review voucher	21st Century Cures Act (P.L. 114-255), 2016[a]	Does not require reauthorization	0
Total			**3,850**

Source: Compiled by CRS, using the FY2027 FDA CJ.

Notes: Individual amounts may not add to the total due to rounding. The user fee amounts in the column "FY2027 Anticipated Collections" are different from the user fee amounts displayed in **Table 1**. This table presents the total amount requested for FY2027 for each user fee program, whereas **Table 1** displays how the user fees are apportioned across FDA program areas. For example, PDUFA fees contribute to the Human Drugs, Devices and radiological health, and Biologics programs; FDA Headquarters; Other Rent and Rent-related activities; and GSA Rental Payments.

a. While the authority for FDA to award priority review vouchers under the medical countermeasures voucher programs sunset on October 1, 2023, the authority for FDA to assess and collect fees for use of the vouchers did not sunset. FDA does not publish anticipated collections under the medical countermeasures voucher program.

b. The Drug Quality and Security Act (P.L. 113-54) authorized FDA to collect fees for the licensure and inspection of certain third-party logistics providers and wholesale drug distributors. According to the FDA FY2023 CJ, this program is still under development.

Table A-2. User Fee Revenue: Authority by FDA Program Area

	Program									
User Fee Authority	**Human Foods**	**Human drugs**	**Biologics**	**Animal drugs & foods**	**Devices & radiological health**	**Tobacco**	**Headquarters & Commissioner's Office**	**GSA rent**	**Other rent and rent related**	***Not shown by program***
Prescription drug (PDUFA)		X	X		X		X	X	X	
Medical device (MDUFMA)			X		X		X	X	X	
Animal drug (ADUFA)				X			X	X	X	
Animal generic drug (AGDUFA)				X			X	X	X	
Tobacco (TCA)						X	X	X	X	
Generic drug (GDUFA)		X	X				X	X	X	
Biosimilars (BsUFA)		X	X				X	X	X	
MQSA					X		X			
Food reinspection	X			X			X	X	X	

	Program									
User Fee Authority	**Human Foods**	**Human drugs**	**Biologics**	**Animal drugs & foods**	**Devices & radiological health**	**Tobacco**	**Headquarters & Commissioner's Office**	**GSA rent**	**Other rent and rent related**	***Not shown by program***
Food & feed recall	X						X	X	X	
VQIP	X						X	X	X	
Third-party auditor	X			X			X	X	X	
Outsourcing facility		X					X	X	X	
Over the Counter Monograph										X
Color certification										X
Export certification										X
Priority review vouchers										X
Medical countermeasures										X

Source: Compiled by CRS, using the FY2027 FDA CJ.

Note: The contributions of the user fee authorities to different FDA programs are denoted by "Xs" in the columns

Appendix B. COVID-19 and FDA Supplemental Appropriations

In FY2020 and FY2021, Congress and the President enacted a series of Coronavirus Disease 2019 (COVID-19)-related supplemental appropriations acts to respond to the pandemic. Across four of the five supplemental appropriations acts, FDA received a total of $218 million in new emergency-designated discretionary funding or directed transfers. This included $196 million to the agency's salaries and expenses account to "prevent, prepare for, and respond to coronavirus domestically and internationally." These funds were to be used for activities such as pre- and post-market work on medical countermeasures (MCMs), emergency use authorizations (EUAs), monitoring of medical product supply chains, advanced manufacturing, and related administrative activities. In addition, the Paycheck Protection Program and Health Care Enhancement Act (PPPHCEA; P.L. 116-139) directed a transfer of $22 million from the Public Health and Social Services Emergency Fund (PHSSEF) to FDA to support activities associated with "diagnostic, serological, antigen, and other tests, and related administrative activities." These four supplemental laws are as follows:

- Division A of the Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123), enacted on March 6, 2020, provided $61 million to FDA for domestic and international efforts "to prevent, prepare for, and respond to coronavirus" to be used for activities such as development of medical countermeasures (e.g., therapeutics, vaccines, and diagnostics), advanced manufacturing of medical products, monitoring of supply chains, and related administrative activities.
- Division B of the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), enacted on March 27, 2020, provided $80 million to FDA "to prevent, prepare for, and respond to coronavirus," for efforts on potential medical product shortages, advanced manufacturing of medical products, and development of needed medical countermeasures, including therapeutics, vaccines and diagnostics, and related administrative activities.
- Division B of the PPPHCEA (P.L. 116-139), enacted on April 24, 2020, provided $22 million to FDA, as a transfer from the PHSSEF account, to support activities associated with "diagnostic, serological, antigen, and other tests, and related administrative activities."
- Division M of Consolidated Appropriations Act, 2021 (P.L. 116-260), enacted on December 27, 2020, provided $55 million to FDA "to prevent, prepare for, and respond to coronavirus, domestically or internationally, of which $9,000,000 shall be for the development of necessary medical countermeasures and vaccines, $30,500,000 shall be for advanced manufacturing for medical products, $1,500,000 shall be for the monitoring of medical product supply chains, $7,600,000 shall be for other public health research and response investments, $1,400,000 shall be for data management operation tools, and $5,000,000 shall be for after action review activities."

In addition to the supplemental appropriations acts listed above, on March 11, 2021, the American Rescue Plan Act of 2021 (ARPA, P.L. 117-2) was enacted through the budget reconciliation process. Section 2304 of ARPA provided $500 million in mandatory funding to the HHS Secretary, to remain available until expended, for various MCM activities at FDA. This includes FDA's evaluation of continued performance, safety, and effectiveness of COVID-19 vaccines,

therapeutics, and diagnostics, including with respect to emerging SARS-CoV-2 variants; facilitation of advanced continuous manufacturing activities related to the manufacture of vaccines and related materials; conduct of inspections related to manufacturing of vaccines, therapeutics, and devices that were delayed or canceled because of COVID-19; review of devices authorized for use for the treatment, prevention, or diagnosis of COVID-19; and oversight of the supply chain and mitigation of COVID-19 MCM shortages.

Because the funds listed in this appendix were provided outside of the regular annual appropriations process, these amounts are not included in the total amounts listed in the text or in **Table 1**.

Author Information

Amanda K. Sarata
Specialist in Health Policy

Hassan Z. Sheikh
Analyst in Health Policy

Joe Angert
Research Assistant

Nora Wells
Analyst in Health Policy

Acknowledgments

Sylvia Bryan, former Research Assistant, provided significant support in the authoring of this fact sheet.

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