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

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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 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 four other program area offices oversee the core functions of the agency: the Office of Medical Products and Tobacco, the Office of Foods and Veterinary Medicine, the Office of Global Regulatory Operations and Policy, and the Office of Operations. The Office of Medical Products and Tobacco includes the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), and the Center for Tobacco Products (CTP). The Office of Foods and Veterinary Medicine includes the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). The National Center for Toxicological Research (NCTR) is housed within the Office of the Commissioner.

FDA's *total program level*, the amount that FDA can spend, is composed of 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 FY2017 and FY2022, FDA's enacted annual *total program level* (excluding amounts enacted in supplemental appropriations measures or in the American Rescue Plan Act) increased from $4.745 billion to $6.248 billion. Over that time period, congressionally appropriated funding increased by almost 21%, while user fee revenue increased by more than 47%. The Administration's FY2023 request for a *total program level* of $6.637 billion would be an increase of more than $388 million (+6%) over the FY2022-enacted amount. This report will be updated with information on FDA funding for FY2023 once legislative action on appropriations for the new fiscal year is completed.

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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 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 beginnings 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 four other program area offices oversee the core functions of the agency: the Office of Medical Products and Tobacco, the Office of Foods and Veterinary Medicine, the Office of Global Regulatory Operations and Policy, and the Office of Operations. The Office of Medical Products and Tobacco includes the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Center for Drug Evaluation and Research (CDER), and the Center for Tobacco Products (CTP). The Office of Foods and Veterinary Medicine includes the Center for Food Safety and Applied Nutrition (CFSAN) and the Center for Veterinary Medicine (CVM). The National Center for Toxicological Research (NCTR) is housed within the Office of the Commissioner.[2]

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 FY2017 through FY2022, as well as the FDA's FY2023 request, by program area (e.g., Foods, Human Drugs), which includes funding for the responsible FDA center (e.g., CFSAN, CDER) and the portion of funding for the FDA-wide Office of Regulatory Affairs (ORA) that is committed to that program area.[3]

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

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

[2] FDA Organization, https://www.fda.gov/AboutFDA/CentersOffices/default.htm.

[3] ORA is the lead office for FDA field activities, conducting inspections of firms producing FDA-regulated products, investigating consumer complaints, and enforcing FDA regulations, among other things. For additional information about ORA, see https://www.fda.gov/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ucm409371.htm.

as *budget authority*.)[4] Second, FDA also is allowed to collect and obligate *user fees*.[5] FDA's 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, which is used for any changes to or purchase 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, 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 FY2022 budget. 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 is authorized to be transferred over a nine-year period (FY2017-FY2025).[8] The law specified that amounts in

[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 user fee programs. See, for example, CRS Report R44961, *FDA Reauthorization Act of 2017 (FDARA, P.L. 115-52)*; CRS Report R44750, *FDA Human Medical Product User Fee Programs*; CRS Report R44864, *Prescription Drug User Fee Act (PDUFA): 2017 Reauthorization as PDUFA VI*; CRS Report R44517, *The FDA Medical Device User Fee Program: MDUFA IV Reauthorization*; and CRS Report R40443, *The FDA Food Safety Modernization Act (*P.L. 111-353*)* (out of print but available to congressional clients upon request).

[6] FY2019 FDA *Justification of Estimates for Appropriations Committees.*

[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.

the account are 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, are to be subtracted from any cost estimates provided for purposes of budget controls. Effectively, the appropriations from the account will not be counted against any spending limits, such as the statutory discretionary spending limits; that is, the amounts appropriated from the account will be considered outside those limits for FY2017 through FY2025.

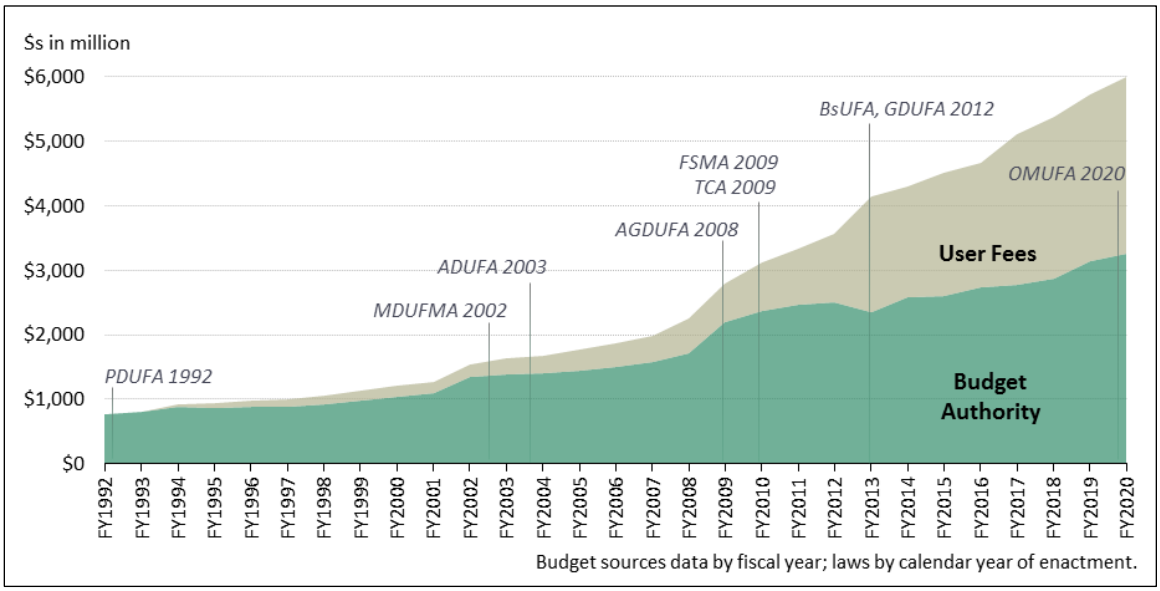
In general, this report focuses on funding provided as part of the regular appropriations process. As such, this report does not include in the total amounts emergency funding provided in supplemental appropriations acts; these supplemental amounts are noted, where applicable, in the **Table 1** notes. *Given the 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 text box summarizing this funding.*

FDA Funding History and FY2022 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 over 45% of the agency's FY2020 total program level (see **Figure 1**).

Figure 1. FDA Spending, by Source, FY1992-FY2020

(in millions of dollars)



Source: Figure created by CRS using the FY1992 through FY2022 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 "Actuals" columns in the FDA CJs, which, according to the FY2005 CJ, reflect FDA's actual spending rather than what was provided in the enacted appropriation. "Actual" amounts beyond FY2020 are not available from the FDA CJs. 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 FY2017 and FY2022, FDA's enacted annual *total program level* (excluding amounts enacted in supplemental appropriations measures or in the American Rescue Plan Act)[9] increased from $4.745 billion to $6.248 billion (see **Table 1**). Over that time period, congressionally appropriated funding increased by almost 21%, while user fee revenue increased by more than 47%. The FY2022-enacted appropriation provides $3.367 billion in *budget authority*, which includes $50 million for the FDA Innovation Account—as specified in the 21st Century Cures Act—as well as an additional $2.881 billion in *user fees*.

The Administration's FY2023 request for a *total program level* of $6.637 billion would be an increase of more than $388 million (+6%) over the FY2022-enacted amount. The FY2023 request proposes $3.703 billion in *budget authority*—an increase of $336 million (+9%) over the FY2022-enacted amount. Included in the $3.703 billion is $50 million for the FDA Innovation Account. **Table 1** includes the FDA Innovation Account money in the total budget authority and program level amounts, consistent with the budget display conventions used in the FDA CJs.

The FY2023 budget request proposes $2.933 billion in user fees—an increase of about $52 million (+2%) over the FY2022-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 $2.933 billion in user fees from currently authorized programs, the FY2023 request includes an additional $104.453 million in *unauthorized* user fees:

- expanded tobacco product fees ($100 million) to include all deemed tobacco products in the tobacco user fee assessments (e.g., electronic nicotine delivery systems [ENDS]),[10] and
- additional export certification fees ($4.453 million), as current export certification fees are capped at $175 per certification, which, according to FDA, is less than the current cost to run the program.[11]

It is estimated that including the proposed fees would bring the FDA's total requested user fee amount to $3.038 billion.

Consistent with the Administration 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 FY2017 through FY2022 and the FY2023 request. The human drugs program comprises the largest portion of FDA's budget (34% in FY2022), followed by the foods program (18% in FY2022), and the tobacco program (11% in FY2022), which is funded solely by tobacco product user fees.

[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 the shaded text box below.

[10] FY2023 FDA *Justification of Estimates for Appropriations Committees*, p. 46. Currently, FDA has the authority to assess and collect user fees from cigarette, roll-your-town tobacco, snuff, chewing tobacco, cigars, and pipe tobacco manufacturers. While FDA has *deemed* certain tobacco products to be under its authority (e.g., ENDS), the agency has determined that it currently does not have the authority to collect user fees from manufacturers of certain deemed products, such as ENDS. For more information see FDA, "Requirements for the Submission of Data Needed To Calculate User Fees for Domestic Manufacturers and Importers of Cigars and Pipe Tobacco," 81 *Federal Register* 28709, May 10, 2016.

[11] The FY2023 request proposes an increase in the statutory cap of export certification fees from $175 to $600 per certification. FY2023 FDA *Justification of Estimates for Appropriations Committees*, p. 46.

Table 1. Food and Drug Administration (FDA) Appropriations

(dollars in millions)

Program Area	FY2017 Enacted	FY2018 Enacted	FY2019 Enacted	FY2020 Enacted	FY2021 Enacted	FY2022 Enacted	FY2023 Request
Foods	**1,037**	**1,053**	**1,071**	**1,100**	**1,110**	**1,145**	**1,232**
BA	1,026	1,042	1,060	1,089	1,099	1,133	1,220
Fees	12	12	11	11	11	12	12
Human drugs	**1,330**	**1,619**	**1,881**	**1,973**	**1,997**	**2,116**	**2,220**
BA	492	496	663	683	689	714	790
Fees	838	1,123	1,218	1,290	1,308	1,402	1,430
Biologics	**340**	**360**	**402**	**419**	**437**	**457**	**475**
BA	215	215	240	252	254	260	275
Fees	124	144	162	167	183	197	200
Animal drugs and feeds	**195**	**198**	**225**	**239**	**245**	**255**	**301**
BA	163	173	179	191	192	202	242
Fees	32	26	46	48	53	53	58
Devices and radiological health	**448**	**507**	**576**	**600**	**628**	**648**	**698**
BA	330	330	387	395	408	420	466
Fees	118	177	190	205	220	228	232
Tobacco products	**596**	**626**	**667**	**662**	**682**	**680**	**677**
Fees	596	626	667	662	682	680	677
Toxicological research	**63**	**63**	**67**	**67**	**67**	**70**	**79**
BA	63	63	67	67	67	70	79
Headquarters/ Commissioner's Office[a]	**285**	**337**	**319**	**319**	**320**	**331**	**358**
BA	185	196	188	185	195	206	228
Fees	100	141	131	134	125	125	130
GSA rent	**232**	**239**	**239**	**241**	**236**	**237**	**239**
BA	170	170	170	171	167	166	166
Fees	62	68	68	69	69	70	73
Other rent, rent-related activities[b]	**164**	173	**174**	**187**	**189**	**193**	**217**
BA	115	115	115	126	130	133	156
Fees	49	58	59	61	59	60	62
Over the Counter Monograph	—	—	—	—	**28**[c]	**25**	**30**
Fees	—	—	—	—	28	25	30

Program Area	FY2017 Enacted	FY2018 Enacted	FY2019 Enacted	FY2020 Enacted	FY2021 Enacted	FY2022 Enacted	FY2023 Request
Export, color certification	**14**	**15**	**15**	**15**	**15**	**16**	**16**
Fees	14	15	15	15	15	16	16
Priority review voucher	**8**	**8**	**8**	**13**	**13**	**13**	**14**
Fees	8	8	8	13	13	13	14
FDA Innovation Account	**20**	**60**	**70**	**75**	**70**	**50**	**50**
BA	20	60	70	75	70	50	50
Buildings & Facilities	**12**	**12**	**12**	**12**	**13**	**13**	**31**
BA	12	12	12	12[d]	13	13	31
Total Budget Authority	**2,791**	**2,872**	**3,150**	**3,246**	**3,285**	**3,367**	**3,703**[e]
Total User Fees	**1,954**	**2,397**	**2,575**	**2,675**	**2,766**	**2,881**	**2,933**[f]
Total Program Level	**4,745**[g]	**5,269**[h]	**5,725**	**5,921**	**6,050**[i]	**6,248**	**6,637**

Sources: The FY2017-FY2023 FDA CJs; the Consolidated Appropriations Act, 2017 (P.L. 115-31); the 2017 Further Continuing and Security Assistance Appropriations Act (P.L. 114-254); the Consolidated Appropriations Act, 2018 (P.L. 115-141); the Consolidated Appropriations Act, 2019 (P.L. 116-6); the Further Consolidated Appropriations Act, 2020 (P.L. 116-94); the Consolidated Appropriations Act, 2021 (P.L. 116-260); the Consolidated Appropriations Act, 2022 (P.L. 117-103) and the accompanying explanatory statements.

Notes: BA=Budget Authority. Individual amounts may not add to subtotals or totals due to rounding. Consistent with the Administration and congressional committee formats, each program area includes funding designated for the responsible FDA center (e.g., the Center for Drug Evaluation and Research or the Center for Food Safety and Applied Nutrition) and the portion budgeted for agency-wide Office of Regulatory Affairs in that area.

a. 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.

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

c. The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136) authorized FDA to assess and collect fees for certain over-the-counter (OTC) drug activities. The FY2023 CJ does not show how this money would be distributed and in what amounts across programs (e.g., human drugs, headquarters).

d. 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."

e. This total does not include the requested $20 million "in new, one-time funding" for cancer moonshot "for FDA to: advance a variety of research, external collaborations and educational outreach programs, continue to support development and regulation of oncology medical products; and, build upon existing programs to advance Moonshot goals to cut today's age-adjusted death rate from cancer by at least 50 percent over the next 25 years and improve the experience of people and their families living with and surviving cancer" (FY2023 FDA *Justification of Estimates for Appropriations Committees*, p. 12).

f. This amount reflects only those user fees that have been *authorized* in legislation when the FY2023 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 FY2023 request proposes an additional $104.366 million in *unauthorized* user fees: additional export certification fees ($4.453 million) and expanded tobacco product fees ($100 million). Including the proposed fees would bring the FDA's total requested user fee amount to $3.038 billion. The indefinite fees are distributed by

program area consistent with the FY2022 Annualized CR column in the All-Purpose Table in the FY2023 FDA *Justification of Estimates for Appropriations Committees.*

g. This total does not include the $10 million provided by Section 752 of P.L. 115-31 (for FY2017), to remain available until expended, for FDA to "prevent, prepare for, and respond to emerging health threats."

h. This total does not include the $94 million provided by Section 778 of P.L. 115-141 (for FY2018), to remain available until expended, for FDA to expand efforts related to processing opioids and other articles imported through international mail facilities of the U.S. Postal Service. This total also does not include $7.6 million in one-time, no-year funding for Hurricane related facilities and related costs included in the Further Additional Supplemental Appropriations for Disaster Relief and Requirement Act, 2018 (P.L. 115-123).

i. 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."

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 for medical products, monitoring of medical product 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, enforcement work against counterfeit or misbranded products, work on Emergency Use Authorizations, pre- and postmarket work on medical countermeasures, therapies, vaccines and research, 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 medical countermeasures 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 text box 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**.

Appendix A. FDA User Fee Authorizations and Anticipated Collections

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

(In Order of FY2023 Anticipated Collections)

User Fee	Initial Authorizing Legislation and Year	Most Recent Reauthorization and Year, and Length of Current Authorization	FY2023 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	1,224
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	550
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	248
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	41
Animal drug	Animal Drug User Fee Act (ADUFA; P.L. 108-130), 2003	Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (P.L. 115-234), 2018 FY2019-2023	32
Over the Counter Monograph	The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), 2020	The Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. 116-136), 2020 FY2021-FY2025	30
Animal generic drug	Animal Generic Drug User Fee Act (AGDUFA; P.L. 110-316), 2008	Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (P.L. 115-234), 2018 FY2019-2023	29

User Fee	Initial Authorizing Legislation and Year	Most Recent Reauthorization and Year, and Length of Current Authorization	FY2023 Anticipated Collections (in millions of dollars)
Mammography	Mammography Quality Standards Act (MQSA; P.L. P.L. 102-539), 1992	Does not require reauthorization	19
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	8
Food reinspection	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	7
Voluntary qualified importer program (VQIP)	Food Safety Modernization Act (FSMA; P.L. 111-353), 2011	Does not require reauthorization	6
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
Medical counter-measures priority review voucher	21st Century Cures Act (P.L. 114-255), 2016[a]	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
Total			**2,933**

Source: Compiled by CRS, using the FY2023 FDA CJ.

Notes: Individual amounts may not add to the total due to rounding. The user fee amounts in the column "FY2023 Anticipated Collections" are different from the user fee amounts displayed in **Table 1**. This table presents the total amount requested for FY2023 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 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 rare pediatric disease and medical countermeasures voucher programs is to sunset on September 30, 2022, and October 1, 2023, respectively, the authority for FDA to assess and collect fees for use of the vouchers does not sunset.

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	**Foods**	**Human drugs**	**Biologics**	**Animal drugs & fees**	**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	
Food & feed recall	X						X	X	X	

	Program									
User Fee Authority	**Foods**	**Human drugs**	**Biologics**	**Animal drugs & fees**	**Devices & radiological health**	**Tobacco**	**Headquarters & Commissioner's Office**	**GSA rent**	**Other rent and rent related**	***Not shown by program***
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 FY2022 FDA CJ.

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

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