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FDA Human Medical Product User Fee Programs

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FDA Human Medical Product User Fee Programs

SUMMARY

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The Food and Drug Administration (FDA) regulates human medical products to ensure they are safe and effective for their intended use in patients. Medical products include prescription and nonprescription drugs, biological products ("biologics"), and medical devices, among others. FDA regulation of these products involves implementation of premarket and postmarket requirements.

Funding of FDA Medical Product Regulation

To fund its regulatory activities, FDA relies on discretionary appropriations from two sources: (1) appropriations from the General Fund of the Treasury and (2) user fees paid by the regulated industry. Many user fee programs administered by FDA are permanently authorized, meaning they do not require reauthorization. Other user fee programs require reauthorization if they are to continue. The latter programs include those that help fund regulatory activities for prescription brand and generic drugs, medical devices, and biosimilar biological products ("biosimilars"). These four human medical product user fee programs have been reauthorized together in legislation on a five-year cycle. The authorizing legislation generally sets a total amount of fee revenue for the program's first year, to be adjusted annually; specifies the fee types that FDA may collect; and requires that certain legal conditions be satisfied in order for FDA to collect and spend user fees. The original authorizing legislation for each of these four medical product user fee programs is as follows:

- The Prescription Drug User Fee Act of 1992 (PDUFA, P.L. 102-571).
- The Medical Device User Fee and Modernization Act of 2002 (MDUFMA, P.L. 107-250), or Medical Device User Fee Amendments (MDUFA).
- The Generic Drug User Fee Amendments of 2012 (GDUFA, Title III of the Food and Drug Administration Safety and Innovation Act [FDASIA], P.L. 112-144).
- The Biosimilar User Fee Act of 2012 (BsUFA, Title IV of FDASIA, P.L. 112-144).

User Fee Reauthorization

Due to the importance of user fees to FDA's budget, reauthorization of the medical product user fee programs often has been considered to be "must pass" legislation. Congress generally uses such a reauthorization bill to address related FDA regulatory concerns. The most recent user fee legislation enacted in September 2022—the FDA User Fee Reauthorization Act of 2022, Division F, Continuing Appropriations and Ukraine Appropriations Act, 2023 (P.L. 117-180)—reauthorized each of the four medical product user fee programs through September 30, 2027.

In exchange for paying user fees, industry receives from FDA a commitment to meet certain performance goals, such as completing premarket review within a specified timeframe. Prior to each five-year reauthorization cycle, FDA and industry negotiate the performance goals, which are finalized in a written agreement. The reauthorization process allows for input from relevant stakeholders and provides opportunity for public comment on the agreement. For the next reauthorization cycle, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires the Health and Human Services (HHS) Secretary to submit the four user fee agreements to Congress by January 15, 2027.

Scope of this Report

This report (1) provides an overview of the framework that governs how FDA assesses and collects medical product user fees; (2) describes each of the user fee programs, including changes made by the most recent reauthorization legislation; and (3) illustrates the total costs of each user fee program, comparing the amounts derived from user fee and nonuser fee appropriations.

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Overview

The Food and Drug Administration (FDA) regulates human medical products to ensure they are safe and effective for their intended use in patients.[1] Medical products include prescription (brand and generic) and nonprescription (over-the-counter) drugs, biologics (and biosimilars), and medical devices. FDA regulation of these products involves both premarket and postmarket regulatory requirements.[2] Premarket requirements, which use a significant portion of the agency's resources, include the review of products and product applications for FDA approval, authorization, or clearance prior to marketing. Postmarket requirements are varied, but may include passive surveillance mechanisms used to monitor the performance of medical products once they are marketed and certain postmarket studies and reporting.

FDA Review of Human Medical Products

Center for Biologics Evaluation and Research (CBER) regulates traditional biologics, such as vaccines.

Center for Devices and Radiological Health (CDRH) regulates medical devices.

Center for Drug Evaluation and Research (CDER) regulates prescription brand-name and generic drugs, over-the-counter drugs, and most therapeutic biologics.

To support these premarket and postmarket activities, the agency relies on discretionary appropriations from two sources: (1) appropriations from the General Fund of the Treasury[3] and (2) user fees paid by each regulated industry. The primary purpose of the user fee programs is to reduce the time necessary to review and make decisions on medical product marketing applications. Lengthy review times affect the industry, which waits to market its products, and patients, who wait to use these products. Some critics of the current scope of the user fee programs are concerned that FDA's mission to protect public health may be compromised if reliance on these fees affects the impartiality of FDA's scientists.

Certain user fee programs are typically reauthorized together in legislation on a five-year cycle, with authority for the actual collection and expenditure of the fees provided each year through the annual appropriations process.[4] These programs include those for prescription drugs, medical devices, generic drugs, and biosimilars.[5] The original authorizing legislation for each of these four user fee programs is as follows:

1. Prescription Drug User Fee Act of 1992 (PDUFA, P.L. 102-571);
2. Medical Device User Fee and Modernization Act of 2002 (MDUFMA, P.L. 107-250), or Medical Device User Fee Amendments (MDUFA);
3. Generic Drug User Fee Amendments of 2012 (GDUFA, Title III of the Food and Drug Administration Safety and Innovation Act [FDASIA], P.L. 112-144); and

[1] FDA also regulates animal drugs and feeds, human foods, dietary supplements, cosmetics, radiological devices, and tobacco products.

[2] For more information, see CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*.

[3] This is the usual source of funding for discretionary appropriations and is often referred to as *budget authority* in FDA budget documents.

[4] For a detailed discussion of the funding sources for the review human medical products, see CRS Report R44582, *Overview of Funding Mechanisms in the Federal Budget Process, and Selected Examples*.

[5] The FDA also has user fee authorities for over-the-counter monograph drugs, animal drugs, tobacco products, priority review vouchers, food reinspection, food recall, voluntary qualified food importer, outsourcing facilities (related to drug compounding), and some wholesale distributors and third-party logistics providers (related to pharmaceutical supply chain security). These other authorities are not addressed in this report.

4. the Biosimilar User Fee Act of 2012 (BsUFA, Title IV of FDASIA, P.L. 112-144).[6]

Appendix A outlines various features of these four user fee programs, and **Appendix B** lists relevant CRS reports related to medical product regulation.

Due to the importance of user fees to FDA's budget, reauthorization of the user fee programs often has been considered to be "must pass" legislation. Congress generally uses such a reauthorization bill to address related FDA regulatory concerns; it therefore serves as an important driver for the ongoing modification of overall agency regulatory policy. The most recent user fee legislation enacted in September 2022—The FDA User Fee Reauthorization Act of 2022 enacted in Division F as part of the Continuing Appropriations and Ukraine Appropriations Act, 2023 (P.L. 117-180)—reauthorized each of the four human medical product user fee programs for five more years, from FY2023 through FY2027. The FDA User Fee Reauthorization Act of 2022 consists of five titles; the first four authorize FDA to collect fees and use the revenue to support specified activities for the review of prescription brand-name drugs and biological products, medical devices, generic drugs, and biosimilar biological products. Title V of the act included limited reauthorizations, through December 2022, of a number of FDA programs. These programs were later reauthorized in the Food and Drug Omnibus Reform Act of 2022 (FDORA, Division FF, Title III, Subtitle A, P.L. 117-328) through FY2027.

A shared element of all four user fee programs is that the user fees are to supplement congressional appropriations, not replace them. The authorizing laws include limiting conditions, known as "triggers," to enforce this goal. FDA may collect and use fees only if the appropriations for specified activities involved in the review of products remains at a level at least equal (adjusted for inflation) to an amount or benchmark specified in each law.[7] Originally, the fees were authorized to be used to support only premarket review activities, allowing FDA to hire additional staff to review premarket applications with the goal of reducing review time. Over time, the scope of allowable activities that may be paid for with user fee revenue has been expanded to include, for example, FDA support of manufacturers' preclinical drug development and certain postmarket activities.

In exchange for paying user fees, industry receives from FDA a commitment to meet certain performance goals, such as completing premarket review within a specified timeframe. Prior to each five-year reauthorization cycle, FDA and industry negotiate the performance goals, which are finalized in a written agreement.[8] The reauthorization process allows for input from relevant

[6] On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act, P.L. 116-136) created a user fee program to fund FDA over-the-counter (OTC) monograph activities (OMUFA). In exchange for FDA collection of OMUFA fees, FDA has agreed to meet certain performance goals (e.g., hiring goals). OMUFA was originally authorized through FY2025 and was reauthorized through FY2030 in Division F, Title V of the Continuing Appropriations, Agriculture, Legislative Branch, Military Construction and Veterans Affairs, and Extensions Act, 2026 (P.L. 119-37). Because this user fee program is authorized through FY2030, its reauthorization schedule diverges from the reauthorization of other medical product user fee programs. For more information, see CRS Report R46985, *FDA Regulation of Over-the-Counter (OTC) Drugs: Overview and Issues for Congress*, and CRS In Focus IF12821, *Over-The-Counter Monograph Drug User Fee Program (OMUFA) Reauthorization*.

[7] Prescription drugs, FFDCA §736(f) and (g); 21 U.S.C. §379h(f) and (g); medical devices, FFDCA §738(h); 21 U.S.C. §379j(h); generic drugs, FFDCA §744B(h) and (i); 21 U.S.C. §379j-42(h) and (i); biosimilars, FFDCA §744H(f); 21 U.S.C. §379j-52(f). Further details on each of these legal conditions are available in the FDA user fee financial reports: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/default.htm.

[8] The four performance goal documents for FY2023 through FY2027 are provided on the FDA website as follows:
PDUFA: https://www.fda.gov/media/151712/download;
GDUFA: https://www.fda.gov/media/153631/download;
MDUFA: https://www.fda.gov/media/158308/download;
BsUFA: https://www.fda.gov/media/152279/download.

stakeholders, including academic experts and representatives of patient and consumer advocacy groups, and provides opportunity for public comment on the agreement. For the next reauthorization cycle, the Federal Food, Drug, and Cosmetic Act (FFDCA) requires the Health and Human Services (HHS) Secretary to submit the four user fee agreements to Congress by January 15, 2027.[9] In each previous reauthorization, Congress has generally accepted unchanged the terms and conditions as negotiated between FDA and the industry.

Congressional authorization for the medical product user fee programs expires at the end of FY2027 (September 30, 2027). The FY2027 reauthorization cycle has begun, with FDA having held a series of public meetings in 2025 and commenced regular meetings with respective industry groups to develop recommendations and performance goals for the next reauthorization.

User Fees and the FDA Budget

FDA's budget has two funding streams: annual appropriations (i.e., discretionary budget authority, or BA) and industry user fees.[10] 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. 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 51% of the agency's FY2026 enacted total program level.[11] **Appendix B** provides information on the relative proportion of costs supported by user fee revenue and appropriations for each of the four user fee programs. The following paragraphs look at the funding for each of the four human medical product user fee programs individually.

Prescription drug user fees were first collected in FY1993 and have comprised an increasing proportion of the FDA's budget that is focused on prescription drug regulation. In FY1993, prescription drug user fees provided 7% of the PDUFA program total costs (nonuser fee appropriations provided 93%);[12] in FY2025 (from the most recent financial report available), user fees covered 77% of PDUFA program total costs (nonuser fee appropriations covered 23%).[13] While most of PDUFA revenue supports activities managed by the Center for Drug Evaluation and Research (CDER), PDUFA revenue also contributes to other FDA organizational components that support the PDUFA program, including the Center for Biologics Evaluation and Research (CBER), the Center for Devices and Radiological Health (CDRH), the Office of Inspections and Investigations (OII), and FDA headquarters.[14]

Medical device user fees were first collected in FY2003 and have comprised an increasing proportion of FDA's budget that is focused on device regulation. In FY2003, medical device user

[9] Prescription drugs, FFDCA §736B(f)(6); 21 U.S.C. §379h-2(f)(6); medical devices, FFDCA §738A(b)(6); 21 U.S.C. §379j-1(b)(6); generic drugs, FFDCA §744C(f)(6); 21 U.S.C. §379j-43(f)(6); biosimilars, FFDCA §744I(f)(6); 21 U.S.C. §379j-53(f)(6).

[10] For more information about the FDA budget generally, and a discussion of user fees within the budget, see CRS Report R44576, *The Food and Drug Administration (FDA) Budget: Fact Sheet*.

[11] P.L. 119-37. See *Congressional Record*, daily edition, vol. 171 (November 9, 2025), p. S8051.

[12] FDA, *Prescription Drug User Fee Act Fiscal Year 1997 Report to Congress*, pp. 5, 10, https://www.fda.gov/media/73916/download.

[13] FDA, *FY 2025 PDUFA Financial Report*, Table 11: Historical Prescription Drug User Fee Obligations by Funding Source as of September 30 for FYs 2021 to 2025, p. 16, at https://www.fda.gov/media/190768/download.

[14] FDA, *FY 2025 PDUFA Financial Report*, Table 12: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2021 to 2025, p. 17.

fees accounted for 11% of the MDUFA program total costs,[15] compared with 60% in FY2025.[16] While most of MDUFA revenue supports activities managed by CDRH, MDUFA revenue also contributes to other parts of FDA that support the MDUFA program including CBER, OII, and FDA headquarters.[17]

In FY2013, the first year that generic drug user fees were collected, user fees accounted for 45% of the GDUFA program total costs compared with 79% in FY2025.[18] While most of GDUFA fee revenue supports activities managed by CDER, GDUFA revenue also contributes to other FDA components that support the GDUFA program, including CBER, OII, and FDA headquarters.[19]

In FY2013, the first year that biosimilar user fees were collected, user fees accounted for 0% of the BsUFA program total costs compared with 60% in FY2025.[20] While most of BsUFA revenue supports activities managed by CDER, BsUFA revenue also contributes to other parts of FDA that support the BsUFA program, including CBER, OII, and FDA headquarters.[21]

Medical Product User Fee Programs

Prescription Drug (Brand) User Fee Program (PDUFA)

Prior to marketing, a manufacturer must submit a new drug application (NDA) or a biologics license application (BLA) to FDA, demonstrating a drug or biologic's safety and effectiveness.[22] FDA scientific and regulatory personnel review the NDA or BLA and prepare written assessments in several categories—medical, chemistry, statistical, pharmacology, clinical pharmacology and biopharmaceutics, risk assessment and risk mitigation, proprietary name, patient labeling—and then decide whether or not to approve the drug or biologic.[23]

In 1992, PDUFA (later called PDUFA I) gave FDA the authority to collect fees from the pharmaceutical industry and use the revenue to support "the process for the review of human drug applications."[24] That five-year authority, which covered both NDAs and BLAs, has been renewed

[15] FDA, *FY 2003 MDUFMA Financial Report*, https://wayback.archive-it.org/7993/20170406060811/https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/FinancialReports/MDUFMA/ucm134568.htm.

[16] FDA, *FY 2025 MDUFA Financial Report*, Table 8: Historical Trend of MDUFA Program Costs by Funding Source as of September 30 for Fiscal Years 2021 to 2025, p. 19, at https://www.fda.gov/media/190764/download.

[17] FDA, *FY 2025 MDUFA Financial Report*, Table 9: Historical Trend of Medical Device User Fee Total Process FTEs Utilized by Organization as of September 30 Fiscal Year 2021 to 2025, p. 20.

[18] FDA, *FY 2025 GDUFA Financial Report*, Table 9: Historical Generic Drug User Fee Obligations by Funding Source as of September 30 for FYs 2021 to 2025, p. 14, at https://www.fda.gov/media/190751/download.

[19] FDA, *FY 2023 GDUFA Financial Report*, Table 10: Historical Trend of Total FTEs Utilized by Organization as of September 30 for FYs 2021 to 2025, p. 14.

[20] FDA, *FY 2025 BsUFA Financial Report*, Table 9: Historical Biosimilar Biological Product User Fee Obligations by Funding Source as of September 30 for FYs 2021 to 2025, p. 16, at https://www.fda.gov/media/190773/download.

[21] FDA, *FY 2025 BsUFA Financial Report*, Table 10: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2021 to 2025, p. 17.

[22] For purposes of PDUFA, the term *prescription drug* includes both small molecule, chemical drugs approved under Section 505 of the FFDCA, as well as biologics (drugs derived from or made in living organisms) licensed under Section 351 of the Public Health Service Act (PHSA).

[23] The listed categories are the sections of drug approval packages posted by FDA; for example, see the November 2016 files regarding Sanofi's Soliqua 100/33 (insulin glargine and lixisenatide), http://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/208673Orig1_toc.cfm.

[24] P.L. 102-571.

on six subsequent occasions, by PDUFA II (1997), PDUFA III (2002), PDUFA IV (2007), PDUFA V (2012), PDUFA VI (2017), and PDUFA VII (2022). PDUFA I authorized FDA to use the fee revenue to fund the "process for the review of human drug applications" and defined what that process encompassed. Congress has amended that definition to expand the scope of activities covered by PDUFA. PDUFA I covered activities that fit within the time window from when a manufacturer submits an NDA or a BLA until FDA makes its decision on that application, (e.g., review of applications, letters from FDA to applicants outlining deficiencies in their applications, and facility inspections). With subsequent amendments made by PDUFA II, III, and IV, FDA may now use PDUFA fees for activities during a drug's preclinical development, clinical trials, and postapproval marketing periods, including postmarket safety activities such as adverse-event data-collection systems, and requirements relating to postapproval studies, labeling changes, and risk evaluation and mitigation strategies.

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 workload changes. PDUFA VII set an annual base revenue of $1.15 billion for FY2023, to be adjusted as specified.[25]

PDUFA I through PDUFA V had required that three types of fees each contribute one-third of the fee revenue every year: an application fee, an annual establishment fee, and an annual product fee.[26] PDUFA VI established a new user fee structure, eliminating the establishment and product fees, and adding a *program fee*.[27] It continued the *application fee*, while eliminating the fee for a supplemental application. PDUFA VI required that user fees be waived or reduced under certain circumstances (e.g., if necessary to protect the public health or if the applicant is a small business submitting its first human drug application). Under this law, 80% of the total prescription drug user fee revenue comes from program fees and 20% from application fees.[28] An application that does not require clinical data for approval is assessed one-half of the application fee that is assessed for an application that does require clinical data.[29]

In addition to setting fee revenue amounts and adjustments for FY2023 through FY2027, PDUFA VII added other changes to the program, including adding allergenic extract products licensed after October 1, 2022, to PDUFA and adding a definition for, and exempting from user fees, "skin-test diagnostic products."[30]

PDUFA Fee Types

Application fee: The sponsor of the application (usually the drug manufacturer) must pay a fee each time it submits an NDA or a BLA for FDA review.

Program fee: The sponsor must pay an annual program fee for each prescription drug product that is identified in an approved application.

[25] FFDCA §736(b) and (c); 21 U.S.C. §379h(b) and (c).

[26] Each manufacturer was required to pay an annual *establishment fee* for each of its manufacturing establishments, an annual *product fee* for each product that fits within PDUFA's definition, and an *application fee*.

[27] PDUFA VI adds the limitation that a person named as the applicant in an approved application cannot be assessed more than five program fees in a fiscal year for prescription drug products identified in such approved application.

[28] FFDCA §736(b)(2); 21 U.S.C. §379h(b)(2).

[29] FFDCA §736(a)(1)(A); 21 U.S.C. §379h(a)(1)(A).

[30] FDA User Fee Reauthorization Act of 2022, §1002(a).

Medical Device User Fee Program (MDUFA)

Medical devices are used to diagnose, treat, monitor, or prevent a disease or condition in a patient. FDA describes medical devices as ranging "from simple tongue depressors and bedpans to complex programmable pacemakers, and closed loop artificial pancreas systems."[31] FDA classifies devices based on their risk to the patient: low-risk devices are class I, moderate-risk are class II, and high-risk are class III. Given the breadth of devices on the market and the different risks they may pose to the consumer, only certain devices are required to undergo premarket review to provide reasonable assurance of safety and effectiveness. The three most common pathways for premarket review of a device include (1) premarket notification (510(k)), (2) premarket approval (PMA), and (3) De Novo classification request. A device's regulatory class generally, but not always, dictates the applicable premarket review pathway.[32]

Unless exempted by statute, class I and class II devices are subject to a premarket notification requirement, and manufacturers must submit a 510(k) premarket notification submission to FDA prior to introducing the device into commercial distribution.[33] To receive 510(k) clearance for a device pursuant to such a submission, a manufacturer must submit certain materials to FDA at least 90 days prior to marketing, demonstrating that the device proposed to be marketed is substantially equivalent to a device already on the market. Class III device manufacturers must submit to the FDA a premarket approval (PMA) application that includes clinical evidence providing reasonable assurance that the device is safe and effective. A successful PMA results in device approval. New devices—that is, devices that were not on the market when the Medical Device Amendments of 1976 (MDA; P.L. 94-295) were enacted—are automatically placed into class III, regardless of the risk posed to the consumer. The De Novo pathway allows for the manufacturer to submit to FDA a request for reclassification of novel low or moderate risk devices into class I or II. Devices that are reviewed through this pathway are granted marketing authorization and may serve as a predicate device for substantial equivalence determinations going forward.

Congress first gave FDA authority to collect user fees from the medical device industry in 2002, and renewed that authority four times subsequently, on five-year cycles: MDUFA II (2007), MDUFA III (2012), MDUFA IV (2017), and MDUFA V (2022). MDUFA I established the application fee for certain premarket submissions (i.e., PMA, 510(k)). In addition to fees for the specified premarket submissions, MDUFA I added application fees for when a manufacturer requests approval of a significant change in the design or performance of a device approved via the PMA pathway; these are called PMA supplements.

MDUFA II added two types of annual fees in order to generate a more stable revenue stream for the agency: (1) establishment registration fees, paid by most device establishments registered with FDA, and (2) product fees paid for class III devices for which periodic reporting is required (periodic reporting fees). MDUFA II also added two additional types of application fees[34] and lowered all existing application fee amounts. MDUFA III changed the definition of "establishment subject to a registration fee," thus increasing the number of establishments paying the fee. MDUFA IV added a new type of application fee (for De Novo classification requests) and

[31] FDA, Medical Devices, "Is the Product a Medical Device," at http://www.fda.gov/medicaldevices/deviceregulationandguidance/overview/classifyyourdevice/ucm051512.htm.

[32] For more information, see CRS Report R47374, *FDA Regulation of Medical Devices*.

[33] This requirement is named after §510(k) in the FFDCA, which establishes the requirement.

[34] The two applications are (1) the 30-Day Notice, used by a manufacturer to request modifications in manufacturing procedures, and (2) the 513(g) application, used by a manufacturer to request information on the classification of a device.

lowered certain small business fees.[35] MDUFA V did not modify or add fees, but it established several new conditional adjustments to the base establishment registration fee (e.g., for performance, hiring)[36] and supports digital health initiatives, the use of real-world evidence/real-world data in regulatory submissions, and increased transparency.

Application fee amounts are set as a percentage of the PMA fee, or base fee. The law sets both the base fee amount for each fiscal year, and the percentage of the base fee that constitutes most other fees (e.g., the 510(k) notification fee is 4.5% of the PMA fee under MDUFA V). [37] The law requires the total revenue amount be adjusted by an inflation adjustment; the base fee is increased accordingly to generate the inflation-adjusted total revenue amount.[38] The establishment fee may be increased as necessary so that total fees collected for the fiscal year generates the total adjusted revenue amount. As most class I and some class II medical devices are exempt from the premarket notification requirement, they thus are not subject to an application fee. Small businesses—those with gross receipts below a statutorily specified amount—pay reduced application fees, and certain fees may be waived in specific cases (i.e., for Humanitarian Device Exemption applications or devices solely for pediatric use).

MDUFA Fee Types

Application fee: The sponsor of a medical device must pay a fee for each submission (e.g., PMA, PMA supplement, a 510(k), De Novo).

Establishment registration fee: Sponsors whose establishment meets the MDUFA definition must pay an annual registration fee.

Periodic reporting fee: Certain class III device sponsors must pay an annual fee for required periodic reporting.

Generic Prescription Drug User Fee Program (GDUFA)

Generic drugs are approved under an abbreviated pathway created by the Hatch-Waxman Act.[39] Rather than replicate and submit data from preclinical and clinical investigations to prove safety and effectiveness, a generic drug company may submit an abbreviated new drug application (ANDA) relying on FDA's previous findings of safety and effectiveness for the reference drug (typically, a brand-name drug). In the ANDA, the applicant must demonstrate that the generic version is pharmaceutically equivalent (i.e., same active ingredient(s), strength, dosage form, route of administration) and bioequivalent to the reference drug.[40] Because the generic sponsor does not have the expense of product development or animal or human clinical trials, it can offer its product at a lower price than the brand-name sponsor does for its product. An ANDA must include proposed labeling for the generic drug, which must be the same as that for the reference drug, with some exceptions.[41] The ANDA also must provide information about the generic's

[35] FFDCA §738(a) and (d); 21 U.S.C. §379j(a) and (d).

[36] See, for example, FFDCA §738(c)(4), (5); 21 U.S.C. §379j(c)(4), (5).

[37] FFDCA §738(a)(2)(A); 21 U.S.C. §379j(a)(2)(A).

[38] FFDCA §738(b) and (c); 21 U.S.C. §379j(b) and (c).

[39] The Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98-417), often referred to as the Hatch-Waxman Act, amended the FFDCA to allow a generic drug manufacturer to submit an abbreviated NDA (ANDA) to the FDA for premarket review.

[40] FFDCA §505(j)(2); 21 U.S.C. §355(j)(2) and 21 C.F.R. §314.94.

[41] FFDCA §505(j)(2)(A)(v); 21 U.S.C. §355j(2)(A)(v).

chemistry, manufacturing, and controls to ensure that the manufacturer can make the drug correctly and consistently.[42]

Due to an increase in the number of ANDAs submitted to FDA for review, and an increase in the number of foreign facilities making generic drugs, prior to the enactment of GDUFA, the agency lacked the resources to keep pace, resulting in a backlog of submitted ANDAs. Generic drug companies submitting ANDAs were not subject to user fees from FDA nor were they included in the scope of activities covered by PDUFA fees.[43]

Congress first gave FDA the authority to collect user fees from generic drug companies in 2012, and renewed that authority two times subsequently, on five-year cycles: GDUFA II (2017) and GDUFA III (2022). GDUFA I authorized FDA to collect fees from generic drug companies to supplement the cost of certain human generic drug activities: review of ANDAs and drug master files (DMFs);[44] approval, deficiency, and complete response letters; facility inspections; monitoring or research; postmarket safety activities; and regulatory science. In exchange, FDA committed to meeting certain performance goals[45] and to taking a "first action" by the end of FY2017 on 90% of the backlog applications that were submitted pre-GDUFA and still pending on October 1, 2012. By September 30, 2017, FDA had taken action on 98% of the ANDAs in the backlog that were pending review as of October 1, 2012.[46] GDUFA I set a total amount of fee revenue for the first year and provided a formula for annual adjustments to that total based on inflation and workload changes. In total, GDUFA I established four fee categories and specified the amount to be derived from each fee type:

- **Backlog fee:** A one-time backlog fee for ANDAs pending as of October 1, 2012.
- **Application Fee:** A one-time fee paid by the sponsor for certain types of ANDAs and prior approval supplements (PAS) (24%).
- **Facility Fee:** An annual fee assessed to certain generic drug finished dosage form (56%) and active pharmaceutical ingredient (14%) manufacturing facilities.
- **DMF Fee:** A fee for certain DMFs associated with human generic drug products (6%).

GDUFA II made modifications to the fee amounts and fee structure to account for increased workload. For example, the total fee revenue amount for the first year of GDUFA II (FY2018) was increased to $493,600,000, to be adjusted annually for inflation.[47] GDUFA II also created a new generic drug applicant program fee, to be paid annually and tiered based on the number of approved ANDAs an applicant owns. It eliminated the prior approval supplement (PAS) fee and

[42] 21 C.F.R. §314.94(a)(9).

[43] For more information, see CRS Report R46778, *The Generic Drug User Fee Amendments (GDUFA): Background and Reauthorization*.

[44] A Drug Master File (DMF) is a voluntary submission to the FDA that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs. The information contained in the DMF may be used to support an Investigational New Drug Application (IND), an NDA, an ANDA, another DMF, an Export Application, or amendments and supplements to any of these; however, it cannot be used as a substitute for an IND, NDA, ANDA, or export application.

[45] FDA, "Generic Drug User Fee Act Program Performance Goals and Procedures," FY2012-FY2017, https://www.fda.gov/media/82022/download.

[46] FDA, "FY2017 Performance Report to Congress for the Generic Drug User Fee Amendments," https://www.fda.gov/media/113302/download.

[47] FFDCA §744B(b) and (c); 21 U.S.C. §379j-42(b) and (c).

provided that fees for foreign generic drug and API[48] facilities are $15,000 higher than for domestic facilities.[49] GDUFA II re-specified the amount to be derived from each fee type: 35% from the new generic drug applicant program fees; 33% from a one-time fee paid by the sponsor of an ANDA upon submission of an application (application fee); 5% from DMF fees; and 20% for finished dosage form, and 7% from API, facilities (facility fee).[50] This restructuring was intended to shift the burden toward annual program fees rather than application fees to provide more predictability in revenue.[51] (The volume of applications fluctuates from year to year, whereas the amount of facilities and approved ANDA holders is relatively stable.)

In addition to setting fee revenue amounts and adjustments for FY2023 through FY2027 and continuing certain reporting requirements, GDUFA III made a number of modifications to the generic drug user fee program, including adjusting the fee amount derived from several GDUFA user fee types[52] and requiring the FDA to establish a capacity planning adjustment that could be utilized to adjust fee amounts "to reflect changes in the resource capacity needs of the Secretary for human generic drug activities," as specified.[53]

GDUFA Fee Types

Drug Master File fee: The sponsor of a Type II API DMF in a generic drug submission must pay an annual fee for each DMF.

Application fee: The sponsor of an ANDA must pay a fee for each submission.

Facility fee: Generic drug manufacturers must pay an annual fee for each manufacturing establishment.

Program fee: The sponsor of an ANDA must pay an annual fee based on the number of approved ANDAs the sponsor owns.

Biosimilar User Fee Program (BsUFA)

A biologic is a therapeutic that is made from living organisms.[54] Compared with conventional chemical drugs, biologics are relatively large and complex molecules. A biosimilar is a biologic that is highly similar, but not structurally identical, to the reference product (i.e., the brand-name biologic).[55]

[48] An API is defined as a substance, or a mixture when the substance is unstable or cannot be transported on its own, intended to be used as a component of a drug and to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the human body; or a substance intended for final crystallization, purification, or salt formation, or any combination of those activities (FFDCA §744A(2)).

[49] FFDCA §744B(b)(2)(C) and (D); 21 U.S.C. §379j-42(b) (2)(C) and (D).

[50] FFDCA §744B(b)(2); 21 U.S.C. §379j-42(b).

[51] FDA, "GDUFA II Fee Structure Summary," https://www.fda.gov/media/101064/download.

[52] FDA User Fee Reauthorization Act of 2022, §3000(b).

[53] FDA User Fee Reauthorization Act of 2022, §3002(c).

[54] PHSA Section 351(i) defines a biologic as "a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings. For more information, see CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*.

[55] This is in contrast to a generic chemical drug, which is considered an exact copy of a brand-name chemical drug (i.e., the reference drug).

The cost of biologics is often higher than small molecule prescriptions drugs.[56] To bring competition to the biologics market, in 2010, the Biologics Price Competition and Innovation Act (BPCIA) was enacted as Title VII of the Patient Protection and Affordable Care Act (ACA, P.L. 111-148). The BPCIA established an abbreviated pathway under Section 351(k) of the PHSA for licensure of biologics that are demonstrated to be "highly similar" (biosimilar) to or "interchangeable" with an FDA-licensed reference product. A company interested in marketing a biosimilar product in the United States must submit to FDA a BLA that provides information demonstrating, among other things, biosimilarity based on data from analytical studies (structural and functional tests), animal studies (toxicity tests), and a clinical study or studies (tests in human patients). FDA may decide, at its discretion, that a certain study or studies are unnecessary in a biosimilar application.[57]

Authority to collect user fees was provided by the Biosimilar User Fee Act of 2012 (BsUFA I, Title IV of FDASIA, P.L. 112-144); this authority was reauthorized in Title IV of FDARA (BsUFA II) in 2017 and again in Title IV of FDAUFRA in 2022. FDA may use BsUFA fees for activities necessary for the review of submissions in connection with biosimilar product development and the review of biosimilar applications.[58] Under BsUFA I, biosimilar product developers were subject to the following fee types: an initial biosimilar biological product development fee; an annual product development fee; a reactivation fee; an application fee; a fee for a supplemental application requiring clinical data; an establishment fee; and a product fee.[59] During the debates leading up to BsUFA I, biosimilars were a new category of medical products, and there was uncertainty around specifics of the program, including the volume of applications FDA would receive each year. Given this, industry and FDA agreed to a fee structure that was modeled after PDUFA. Rather than establishing a total revenue amount for each fiscal year and annual adjustments, under BsUFA I, the individual fee types were set in relation to PDUFA fees for each fiscal year. Specifically, the initial and annual product development fee rates for a fiscal year were to be equal to 10% of the PDUFA fee for an application requiring clinical data for that fiscal year, and the reactivation fee was equal to 20% of the PDUFA fee for an application requiring clinical data for that fiscal year. The application, establishment, and product fee rates under BsUFA I were set as equal to the application, establishment, and product fee rates under PDUFA, respectively.[60]

BsUFA II set the total fee revenue amount for FY2018 at $45,000,000, to be adjusted for updated workload estimates. BsUFA II also provided that the total revenue amounts for FY2019 through FY2022 are based on a formula that takes into account the annual base revenue for the fiscal year, a new inflation adjustment, a new capacity planning adjustment, and the operating reserve for the fiscal year.[61] BsUFA II removed the establishment fee and replaced it with a new biosimilar biological product program fee, stipulating that product sponsors shall not be assessed more than five biosimilar biological product program fees for a fiscal year per application. BsUFA II removed the supplement application fee and changed the application fee by no longer reducing the application fee by the cumulative amount of previously paid fees for the product. The biosimilar application fee may be waived for the first such application from a small business, defined as an entity, including affiliates, with fewer than 500 employees that does not have an

[56] Favour Danladi Makurvet, "Biologics vs. small molecules: Drug costs and patient access," *Medicine In Drug Discovery*, vol. 9 (March 2021), p. 4.

[57] PHSA §351(k)(2)(A); 42 U.S.C. §262(k)(2)(A).

[58] FFDCA §744G(9) and (13); 21 U.S.C. §379j-51(9) and (13).

[59] P.L. 112-144, §402.

[60] Ibid.

[61] FFDCA §744H(b) and (c); 21 U.S.C. §379j-52(b) and (c).

approved drug or biosimilar product introduced into commerce.[62] FDA must determine the percentage of the total revenue amount for a fiscal year to be derived from the (1) initial and annual product development fees and reactivation fee, (2) application fee, and (3) program fee.[63]

In addition to setting fee revenue amounts and adjustments for FY2023 through FY2027, BsUFA III made a number of other modifications to the biosimilar user fee program, including adding a strategic hiring and retention adjustment,[64] specifying that FDA may administratively remove a biosimilar license from the biological product development (BPD) for failure to pay an annual fee for a period of two consecutive years, as specified,[65] and specifying when a discontinued product is exempt from the biosimilar biological product program fee.[66]

BsUFA Fee Types

Initial product development fee: The sponsor of a biosimilar must pay a fee for development meetings with FDA.

Annual product development fee: The sponsor of a biosimilar must also pay an annual fee while the biosimilar is in the development program.

Reactivation fee: A sponsor that discontinues participation in the biosimilar development program must pay a reactivation fee to resume development.

Application fee: The sponsor must pay a fee each time it submits a new biosimilar application.

Program fee: The sponsor of a biosimilar biological product application must pay an annual program fee.

[62] FFDCA §744H(d); 21 U.S.C. §379j-52(d).

[63] FFDCA §744H(b)(3)(A); 21 U.S.C. §379j-52(b)(3)(A).

[64] FFDCA §744H(c); 21 U.S.C. §379j-52(c).

[65] FFDCA §744H(a)(1)(E); 21 U.S.C. §379j-52(a)(1)(E).

[66] FFDCA §744H(a)(3); 21 U.S.C. §379j-52(a)(3).

Appendix A. FDA Human Medical Product User Fee Programs

Table A-1. FDA Human Medical Product User Fee Programs

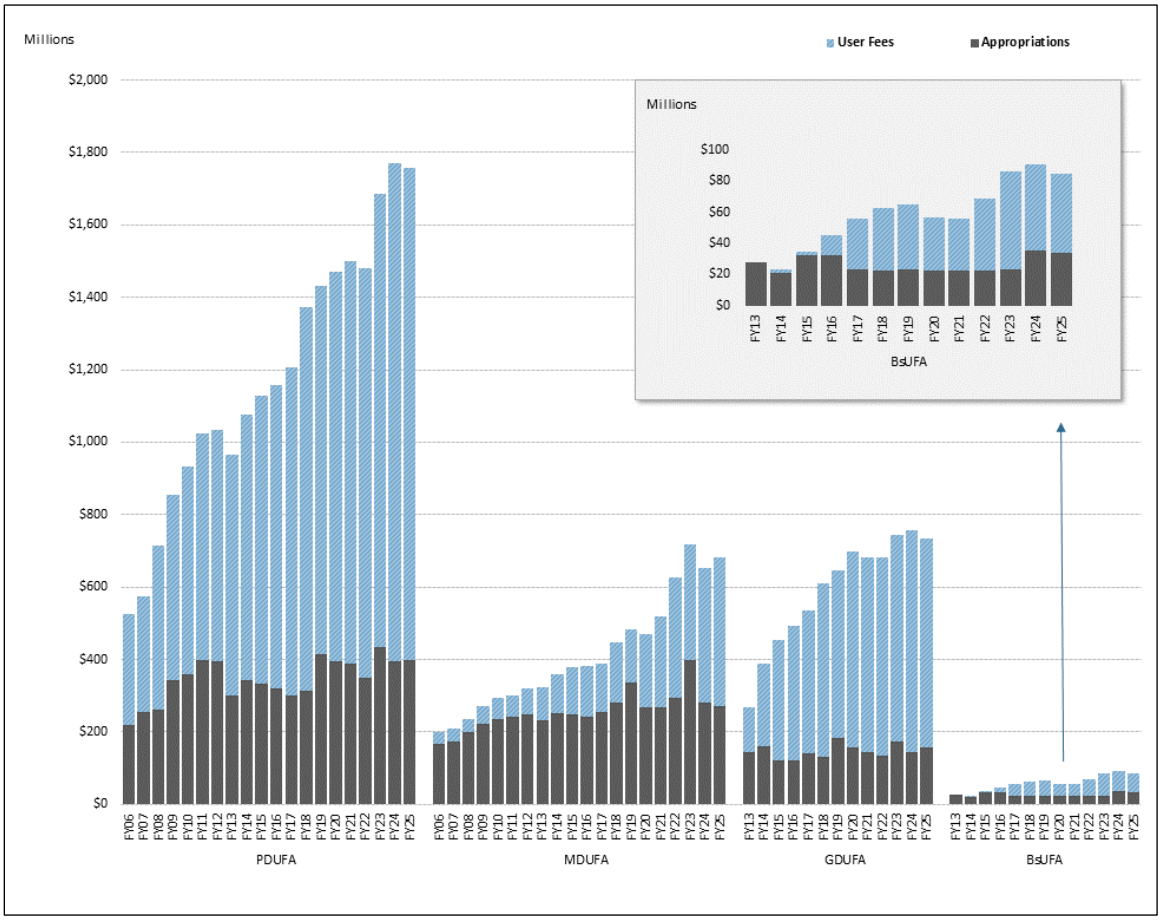
	PDUFA		MDUFA		GDUFA		BsUFA	
Original authorizing legislation	Prescription Drug User Fee Act of 1992 (P.L. 102-571)		Medical Device User Fee and Modernization Act of 2002 (P.L. 107-250)		Generic Drug User Fee Amendments of 2012 (Title III of FDASIA, P.L. 112-144)		Biosimilar User Fee Act of 2012 (Title IV of FDASIA, P.L. 112-144)	
Number of authorizations	7		5		3		3	
Sections in FFDCA (USC)	735, 736, 736B (21 U.S.C. 379g; 379h; 379h–2)		737, 738, 738A (21 U.S.C. 379i; 379j; 379j–1)		744A, 744B, 744C (21 U.S.C. 379j–41; 379j–42; 379j–43)		744G, 744H, 744I (21 U.S.C. 379j–51; 379j–52; 379j–53)	
Percent of program budget paid by user fees in FY2025	77%		60%		79%		60%	
Total FTEs in FY2025	5,153		2,048		2,187		239	
Fee schedule for FY2026	Application w/ clinical data	$4,682,003	PMA, PDP, PMR, BLA	$579,272	ANDA	$358,247	Initial BPD	$10,000
			BLA efficacy supplement	$579,272	DMF	$102,584	Annual BPD	$10,000
	Application w/o clinical data	$2,341,002	Panel-track supplement	$463,418	API domestic facility	$43,549	Reactivation	$20,000
			De Novo	$173,782	API foreign facility	$58,549	Application w/ clinical data	$1,200,794
			180-day supplement	$86,891	FDF domestic facility	$238,943		
	Program	$442,213	Real-time supplement	$40,549	FDF foreign facility	$253,943	Application fee w/o clinical data	$600,397
			510(k) submission	$26,067	CMO domestic	$57,346	Program	$209,097
			30-Day Notice	$9,268	CMO foreign	$72,346		
			513(g) request for classification	$7,820	Program large	$1,918,377		
			Periodic report	$20,275	Program medium	$767,351		
			Establishment	$11,423	Program small	$191,838		

Source: FY2025 FDA User Fee Financial Reports; 90 *Federal Register* 35866, *Prescription Drug User Fee Rates for Fiscal Year 2026*, July 30, 2025; 90 *Federal Register* 35895, *Medical Device User Fee Rates for Fiscal Year 2026*, July 30, 2025; 90 *Federal Register* 35877, *Generic Drug User Fee Rates for Fiscal Year 2026*, July 30, 2025; 90 *Federal Register* 35872, *Biosimilar User Fee Rates for Fiscal Year 2026*, July 30, 2025.

Notes: ANDA, abbreviated new drug application; API, active pharmaceutical ingredient; BLA, biologics license application; BPD, biosimilar biological product development; CMO, Contract Manufacturing Organization; DMF, drug master file; FDASIA, FDA Safety and Innovation Act of 2012; FDF, finished dosage form; FFDCA, Federal Food, Drug, and Cosmetic Act; FTE, full-time equivalent (employees); PDP, product development protocol; PMA, premarket approval application; PMR, premarket report; USC, *United States Code*; w/, with; w/o, without. The MDUFA fees listed are the standard fees, not the small business fees.

Appendix B. User Fees and Appropriations

Figure B-1. FDA Human Medical Product User Fee Programs: Total Costs, by Funding Source



Sources: Graphic created by CRS using data from FY2025 FDA User Fee Financial Reports at https://www.fda.gov/about-fda/user-fee-reports/user-fee-financial-reports; PDUFA Financial Report, Table 11, p. 16; MDUFA Financial Report, Table 8, p. 19; GDUFA Financial Report, Table 9, p. 14; BsUFA Financial Report, Table 9, p. 16.

Appendix C. Selected CRS Products Related to FDA Regulation of Human Medical Products

- CRS Report R41983, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*
- CRS Report R47374, *FDA Regulation of Medical Devices*
- CRS Report R44620, *Biologics and Biosimilars: Background and Key Issues*
- CRS In Focus IF11083, *Medical Product Regulation: Drugs, Biologics, and Devices*
- CRS Report R44576, *The Food and Drug Administration (FDA) Budget: Fact Sheet*
- CRS In Focus IF11389, *FDA Regulation of Laboratory-Developed Tests (LDTs)*
- CRS Insight IN12657, *FDA Oversight of General Wellness Products*
- CRS In Focus IF11056, *Prescription Drug Importation*
- CRS In Focus IF12821, *Over-The-Counter Monograph Drug User Fee Program (OMUFA) Reauthorization*
- CRS In Focus IF12605, *The Orphan Drug Act: Legal Overview and Policy Considerations*

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