Financial Report to Congress

Generic Drug User Fee Amendments

FY 2022

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Executive Summary

The Generic Drug User Fee Amendments (GDUFA) to the Federal Food, Drug, and Cosmetic Act, as amended, require the Food and Drug Administration (FDA) to report annually on the financial aspects of GDUFA implementation. This is the fifth report under the second authorization of GDUFA (GDUFA II) and covers fiscal year (FY) 2022.

GDUFA specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend GDUFA user fees:

1. FDA's total appropriations for salaries and expenses (excluding user fees) must be equal to, or greater than, FDA's FY 2009 appropriations for salaries and expenses (excluding user fees) multiplied by the adjustment factor.

2. The fee amounts FDA may collect must be specified in appropriation acts.

3. FDA must allocate a minimum of $97,000,000 of appropriations (excluding user fees) multiplied by the adjustment factor, and these funds shall be available to defray the costs of human generic drug activities.

FDA met the three legal conditions in FY 2022, and this report explains how these legal conditions were satisfied. The statements and tables in the report provide data on human generic drug user fee collections, expenditures, and carryover, as well as comparative data from prior years.

In FY 2022, FDA had net collections of $546 million in human generic drug user fees, spent $548 million in user fees for the human generic drug review process, and carried $131 million forward for future fiscal years.

GDUFA user fees and non-user fee appropriations in FY 2022 supported 2,099 full-time equivalents, including salaries and operational expenses, to support human generic drug activities. Detailed program accomplishments can be found in the FY 2022 GDUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation and use of human generic drug user fees by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2021, through September 30, 2022. This report presents the legal conditions that FDA must satisfy to collect and spend human generic drug user fees each year and documents how FDA determined that it met those requirements. In addition, this report presents summary statements of fiscal year (FY) 2022 fee collections, carryover, obligations of user fees, and total costs of human generic drug activities from both Generic Drug User Fee Amendments (GDUFA) fees and non-user fee appropriations.

B. Report Requirements

In accordance with section 744C(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will publish an annual financial report on the implementation of the authority for user fees during each fiscal year and the use by FDA of the fees collected for each fiscal year. The purpose of this report is to meet these requirements.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year (September 30). Additional details on what is required to be included in this report are included in **Appendix A**.

Management Discussion

C. Organization Background

FDA is responsible for protecting public health by helping to ensure the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public's health by helping to speed innovations that make medical products more effective, safe, and affordable and by helping the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering the development of medical products to respond to deliberate and naturally emerging public health threats.

Program Organization

There are four major FDA components that support the GDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

Exhibit 1 provides an overview of the mission for each of these components.

Exhibit 1: User Fee Program Components

Component	Mission
CDER	Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients.
CBER	Ensures the safety, purity, potency, and effectiveness of biological products including vaccines, allergenics, blood and blood products, and cells, tissues, and gene therapies for the prevention, diagnosis, and treatment of human diseases, conditions, or injury.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and by minimizing the risk(s) associated with those products.
HQ	Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.

User Fee Governance

The Agency's expanding level of user fees, the reporting of the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This governance includes an understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA leverages the User Fee Financial Management Committee (UFFMC) for user fee governance. The UFFMC consists of senior financial, business operations, and program experts across the Agency that evaluate user fee resource needs, develop financial allocation plans, and forecast resource requirements – both programmatic and administrative – to support user fee financial decisions. The UFFMC is responsible for providing oversight and support of appropriate standards and policies to ensure FDA's compliance with sound financial management practices as well as ensuring FDA's compliance with statutory provisions that authorize FDA to collect and spend user fees. The UFFMC receives policy guidance and strategic direction directly from FDA's Executive Committee relative to how the Agency will forecast and react to industry trends, plan and manage its research agenda in support of the user fee programs, and forecast its user fee workload. The UFFMC advises the Executive Committee and other Center and Office-level bodies on a variety of financial and performance-related topics.

D. User Fee Background and Structure

Under GDUFA, FDA assesses and collects fees from human generic drug manufacturers to help fund human generic drug activities. The FD&C Act, as amended by the FDA Reauthorization Act of 2017 (FDARA), authorizes FDA to assess and collect fees from industry to supplement non-user fee appropriations that the Agency spends on human generic drug activities.

FDARA included the Generic Drug User Fee Amendments of 2017, also known as GDUFA II, which extended the program from October 1, 2017, through September 30, 2022. This 5-year reauthorization ensures continued funding for FDA from FY 2018 through FY 2022 to support program innovation, evaluation, and improvement. GDUFA II continues to enable FDA to assess user fees to help fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. This delivers tremendous public health benefits by helping to provide the public access to safe, affordable, effective, and high-quality generic drugs.

Under GDUFA II, some key changes were made to the GDUFA fee structure:

1. The filing fee for a prior approval supplement is no longer incurred.

2. No facility or abbreviated new drug application (ANDA) applicant will be charged an annual facility fee until an ANDA is approved.

3. Domestic contract manufacturing organizations (CMOs) will pay one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.

4. A person and its affiliates will pay one annual program fee commensurate with the number of approved ANDAs that the firm and its affiliates collectively own.

Exhibit 2 outlines the GDUFA II user fee structure.

Exhibit 2: GDUFA II's Fee Structure

Fee Type		Definition
Abbreviated New Drug Application (ANDA)		An ANDA filing fee is incurred upon submission of an abbreviated new drug application.
Type II Domestic and Foreign Active Pharmaceutical Ingredients (API) Drug Master File (DMF)		The one-time DMF fee is incurred on whichever of the following dates occurs earlier: (1) the first time a generic drug submission references that DMF by an initial letter of authorization on or after October 1, 2012, or (2) the date the DMF holder requests the initial completeness assessment.
Program	*Small, Medium, Large*	Each person and affiliate will be assessed an annual fee depending on the number of approved ANDAs in the person's portfolio.
Facility	*Domestic and Foreign (API)*	An API facility fee is owed by each person who owns a facility that is identified in (1) at least one approved generic drug submission in which the facility is approved to produce one or more APIs or (2) in a Type II API drug master file referenced in at least one approved generic drug submission. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.
	Domestic and Foreign Finished Dosage Form (FDF)	An FDF facility fee is owed by each person who owns a facility that is identified in at least one generic drug submission that is approved to produce one or more FDFs of a human generic drug. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.
	Domestic and Foreign Contract Manufacturing Organization (CMO)	An annual CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA, where the facility is not identified in an approved ANDA held by the owner of that facility or its affiliates. An additional $15,000 is assessed for a facility located outside the United States and its territories and possessions.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation. The fee amounts are to be published in the *Federal Register* each year, typically at the beginning of August.[1]

[1] See the GDUFA user fee rates at https://www.fda.gov/industry/fda-user-fee-programs/generic-drug-user-fee-amendments.

GDUFA user fees collected are not a fee-for-service. The user fees that are collected are pooled and may be used for the allowable activities as defined in the FD&C Act. Refer to **Appendix B** for a detailed list of allowable and excluded activities.

Appendix C provides more information on the history of the user fee program.

E. Legal Conditions

The FD&C Act, as amended by GDUFA specifies that three legal conditions must be satisfied each year for FDA to collect and spend human generic drug user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met.

Exhibit 3: GDUFA's Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2022 Salaries and Expenses Appropriation (excluding user fees) be greater than or equal to FDA's Salaries and Expenses Appropriation (excluding user fees) for FY 2009 multiplied by the adjustment factor for inflation.
	Met By	FDA's FY 2022 total appropriation for salaries and expenses (excluding user fees) was $3,304,145,000, whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was $2,344,843,262 after applying the FY 2022 adjustment factor. Thus, the first legal condition was satisfied.
2	Description	The fee amounts FDA may collect for each fiscal year must be specified in that year's user fee appropriation acts.
	Met By	The Consolidated Appropriations Act, 2022 (Public Law 117-103), which the President signed on March 15, 2022, made appropriations through September 30, 2022, for the Salaries and Expenses account of FDA. It specified that $539,656,000 shall be derived from human generic drug user fees and that human generic drug user fees collected in excess of this amount, if any, are appropriated for FDA. Thus, the second legal condition was satisfied.
3	Description	The third condition requires a minimum spending from appropriations, excluding user fees, on human generic drug activities. The minimum spending from such appropriations is $97,000,000 multiplied by the adjustment factor defined in section 744A(3) of the FD&C Act applicable to the fiscal year involved.
	Met By	The specified minimum level for FY 2022 is $111,551,649. In FY 2022, FDA obligated $133,415,075 exclusive of user fees, for the GDUFA program. As FDA spent more than the specified minimum amount in FY 2022, the third legal condition was satisfied.

The legal conditions as stated in the FD&C Act and details on the adjustment factor are included in **Appendix D**.

F. Strategic Plan

Under GDUFA II, FDA continued to modernize the generic drug program by focusing efforts on improving the efficiency, quality, and predictability of the generic drug review process. FDA will continue to expand upon improvements made in the following areas:

Strengthening development and review of hard-to-genericize complex products

- FDA will continue to implement the "pre-ANDA" program for complex products, which features product development, pre-submission, and mid-review cycle meetings to help clarify regulatory expectations early in product development and during application review.

Continuing support and development of business processes to increase first-cycle approvals and to reduce the time to approval by increasing communication and collaboration between FDA and industry

- FDA will continue the "controlled correspondence" process that allows generic drug developers to ask questions prior to ANDA submission.

- FDA will continue mid-cycle communications during the review of an original ANDA when further information or clarification is needed or would be helpful to allow completion of FDA's review.

Continuing implementation of FDA's Drug Competition Action Plan (DCAP), which focuses on developing and implementing initiatives to further expedite the availability of generic drugs

- FDA continues work to improve the efficiency of the generic drug development, review, and approval process.

- FDA pursues efforts to maximize scientific and regulatory clarity with respect to complex drugs.

- FDA continues to work to close loopholes that allow brand-name drug companies to "game" FDA rules in ways that delay the generic competition Congress intended.

G. Performance Summary

The Generic Drug Review performance measure focuses on process enhancements resulting from the GDUFA program. The goals of the GDUFA program are to enhance efficiency in the generic drug review process, promote transparency in communications between FDA and generic drug applicants, and enhance access to high-quality, lower-cost generic drugs. This investment in the Generic Drug Review program is reflected in the performance target, which increased from 60 percent of standard original ANDA submissions reviewed in 15 months in FY 2015 to 90 percent reviewed in 10 months in FY 2017 through FY 2022. Workload associated with maintaining these review goals varies from year to year and has a substantial effect on finances. Preliminary data on FDA's progress in meeting FY 2022 goals are presented below. Refer to the FY 2022 GDUFA Performance Report for additional details.

In FY 2022, FDA approved 722 ANDAs and tentatively approved 183 ANDAs.[2] Under GDUFA II,[3] FDA committed to review and act on 90 percent of standard original ANDAs within 10 months of the date of ANDA submission; as of September 30, 2022, FDA met 100 percent of the goals of such applications and 100 percent of the goals for priority original ANDA submissions with an 8-month goal date.[4] As of September 30, 2022, FDA met 99 percent of the goals pertaining to prior approval supplements if a pre-approval inspection was not required. Under GDUFA II, FDA committed to review and respond to 90 percent of all standard controlled correspondence within 60 days of the date of submission and 90 percent of all complex controlled correspondence within 120 days of the date of submission. As of September 30, 2022, FDA has met the goal for 99 percent of all standard controlled correspondence and 100 percent of all complex controlled correspondence.

Under GDUFA II, FDA took steps to foster earlier development of guidances, which were intended to share the Agency's thoughts on key aspects that should be addressed in related ANDA submissions. In FY 2022, FDA issued three draft guidances for industry and two final guidances for industry on topics applicable to multiple products and 110 new guidances and 67 revised guidances with product-specific recommendations; 58 of these product-specific-guidances were for complex products (38 new and 20 revised). FDA also issued four Manuals of Policies and Procedures, engaged in outreach efforts to educate and inform industry participants and other stakeholders about GDUFA and the generic drugs program, produced podcasts, held regulatory science public meetings and workshops focusing on complex generic drug development, and held several webinars.

Financial Information

This section provides an overview of the program financials for GDUFA for FY 2021 and FY 2022. These financials include user fee revenues, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

H. User Fee Program Financials

Table 1 represents a summary of the GDUFA financial position for FY 2021 and FY 2022. The financial notes included in the table can be found in **Appendix E.**

[2] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/generic-drugs-program-activities-report-monthly-performance.
[3] The performance numbers provided here are for the FY 2022 receipt cohort. These are preliminary numbers that will be updated in the FY 2023 Performance Report.
[4] Under GDUFA II, FDA committed to review and act on 90 percent of priority original ANDAs within 8 months of the date of ANDA submission if the applicant meets the requirements of a Pre-submission Facility Correspondence.

Table 1: Human Generic Drug Collections, Obligations, and Carryover for FYs 2021 and 2022

Budgetary Resources	Notes	FY 2021	FY 2022
Target Revenue	Note 1	**$520,209,000**	**$539,656,000**
Total Carryover, Beginning of Year		$156,731,582	$127,223,404
Net Collections		$500,205,882	$545,842,834
Recoveries	Note 2	$6,535,880	$6,132,460
Total Budgetary Resources		**$663,473,344**	**$679,198,698**

Obligations	Notes	FY 2021	FY 2022
Total Payroll and Operating	Note 3	$455,785,469	$457,133,185
Total Rent	Note 4	$23,037,004	$21,595,013
Total Shared Services	Note 5	$57,427,467	$69,258,739
Total Obligations		**$536,249,940**	**$547,986,937**

Carryover	Notes	FY 2021	FY 2022
Total Carryover, End of Year		**$127,223,404**	**$131,211,761**

Numbers have been rounded to the nearest dollar.
Target Revenue has been rounded to the nearest thousand dollar.

Budgetary Resources: The "Total Budgetary Resources" component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover and additional user fee collections). The "Target Revenue" is the annual revenue amount established when fees for the fiscal year are set. The "Net Collections" are the amounts collected during the fiscal year, net of refunds that have taken place (see section I).

GDUFA II specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation. FDA has applied those factors in the target revenue for annual fee setting (see **Table 2**).

Obligations: The obligations component of **Table 1** shows the annual expenditure of GDUFA fee funds broken out into major expense categories. GDUFA fees may be expended only for costs to support "human generic drug activities," as defined in GDUFA II. For more information on the allowable and excluded costs, see **Appendix B**.

Carryover: GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the GDUFA program in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "GDUFA carryover." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations, so FDA can continue program operations under financial constraints.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for FY 2022. The financial notes referenced in this table can be found in **Appendix E.**

FDA assumes, for planning purposes, that net collections will equal the target revenue amount. Net collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year.

Table 2: Human Generic Drug User Fee Revenue for FY 2022

Target Revenue	Notes	FY 2022
Base Amount		$520,208,640
Inflation Adjustment	Note 6	$11,158,996
Final Year Adjustment	Note 9	$8,288,102
Target Revenue Total	**Note 1**	**$539,656,000**

Numbers have been rounded to the nearest dollar.
Target Revenue numbers have been rounded to the nearest thousand dollars.

The process for setting the annual target revenue is defined in the statute. The base amount for FY 2022 is specified in the statute and then adjusted for inflation. For FY 2022, FDA may, in addition to the inflation adjustment, further increase the fee revenue and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2023. FDA decided to make the final year adjustment to allow for 7 weeks of operating reserves.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2022, but received in FY 2023, is attributed to FY 2022 collections.

GDUFA specifies that fees are to be collected for ANDAs, DMFs, facilities, and the generic drug applicant program fees. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. Net Collections differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single year (e.g., FY 2022) across multiple fiscal years. Transactions such as late collections or refunds processed in a different fiscal year will be displayed in **Tables 3a, 3b,** and **3c** (e.g., a refund processed during FY 2023 for an FY 2022 payment) while other data tables use FY data that solely show the activity within that single fiscal year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Under GDUFA, fees collected and appropriated but not spent by the end of the fiscal year continue to remain available for FDA to spend in future years because they are

classified as no-year funding. The funds carried over from year to year are described in **Section K – User Fee Carryover**.

Tables 3a, 3b, and **3c** outlines GDUFA's collections by fee source and cohort year. Refer to **Section D** for more background and information on the GDUFA II fee structure.

Table 3a: Human Generic Drug User Fee Collections by Fee Source for Cohort Year 2021

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$171,668,970	$152,743,418	-11%
Human Generic Drug Program Fees	$182,073,150	$180,281,709	-1%
Facility Fees	$140,456,430	$140,052,933	0%
DMF Fees	$26,982,800	$27,478,953	2%
Total Collections	**$521,181,350**	**$500,557,013**	**-4%**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Human Generic Drug User Fee Rates for Fiscal Year 2021.

Table 3b: Human Generic Drug User Fee Collections by Fee Source for Cohort Year 2022

Fees Collected	Estimated†	Actual	% Diff
Application Fees	$178,086,480	$183,953,548	3%
Human Generic Drug Program Fees	$188,879,600	$184,847,376	-2%
Facility Fees	$145,707,120	$150,963,074	4%
DMF Fees	$26,982,800	$25,633,584	-5%
Total Collections	**$539,656,000**	**$545,397,582**	**1%**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the Human Generic Drug User Fee Rates for Fiscal Year 2022.

Table 3c: Human Generic Drug User Fees Receivable by Fee Source for Cohort Years 2021 and 2022

FEES RECEIVABLE	Cohort Year 2021 Actual	Cohort Year 2022 Actual
Application Fees	$393,736	$56,448
Human Generic Drug Program Fees	$3,322,378	$5,415,462
Facility Fees	$1,217,126	$1,541,203
DMF Fees	$0	$149,904
Total Receivables	**$4,933,240**	**$7,163,017**

Numbers have been rounded to the nearest dollar.

J. User Fee Obligations

GDUFA fees may be expended only for costs necessary to support "human generic drug activities," as defined in section 744A(9) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix B.**

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years. The financial notes can be found in **Appendix E.**

Table 4: Human Generic Drug User Fee Obligations by Expense Category for FYs 2021 and 2022

User Fee Obligations	Notes	FY 2021	FY 2022
Payroll & Operating	Note 3		
CBER		$118,344	$0
CDER		$384,542,262	$377,913,169
ORA		$41,354,289	$46,585,741
HQ		$29,770,574	$32,634,275
Total Rent	Note 4	$23,037,004	$21,595,013
Total Shared Services	Note 5	$57,427,467	$69,258,739
Total Obligations		**$536,249,940**	**$547,986,937**

Numbers have been rounded to the nearest dollar.

Total obligations include payroll and operating, rent, and shared services costs. The details of each component of total obligations are as follows:

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which GDUFA fees may be expended, as set forth in the statute. These allowable activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the GDUFA program.

- **Rent:** This is paid to the General Services Administration for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rental rates vary based on the type and location of the space provided.

- **Shared Services:** FDA has several shared service organizations, such as human resources and information technology (IT), that provide support across the user fee programs.

Under GDUFA II, FDA committed to advance scientific efforts to develop new human generic drug products and novel dosage forms. Through its regulatory science initiatives, FDA continues to work on developing tools, standards, and approaches to assess these products and facilitate the path to market approval.

One example of FDA's commitment to this program has been its product-specific guidances and recommendations with respect to regulatory submissions (e.g., pre-

ANDA meeting requests and controlled correspondence). As part of the pre-ANDA program, FDA developed and published 177 new and revised product-specific guidances in FY 2022. These product-specific guidances have provided industry with both draft recommendations on the design of bioequivalence studies and scientific advice pertaining to FDFs and drug substances (APIs) that can be used in the development of generic complex and non-complex drugs.

In addition to serving as the scientific basis for the development of product-specific guidances and specific pre-ANDA communications, research outcomes are published in peer-reviewed scientific literature, presented and discussed at major medical and scientific meetings, and contribute to FDA's general guidance development. Since FY 2013, FDA has awarded 203 research contracts and grants. Fifteen new external contracts and grants were awarded in FY 2022, in addition to the 28 ongoing projects receiving funding. A complete list of FY 2013 through FY 2022 awards can be found at https://www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects.

For historical context, **Table 5** provides the total amount spent for the past 5 fiscal years by FDA and by each FDA organization on the GDUFA program.

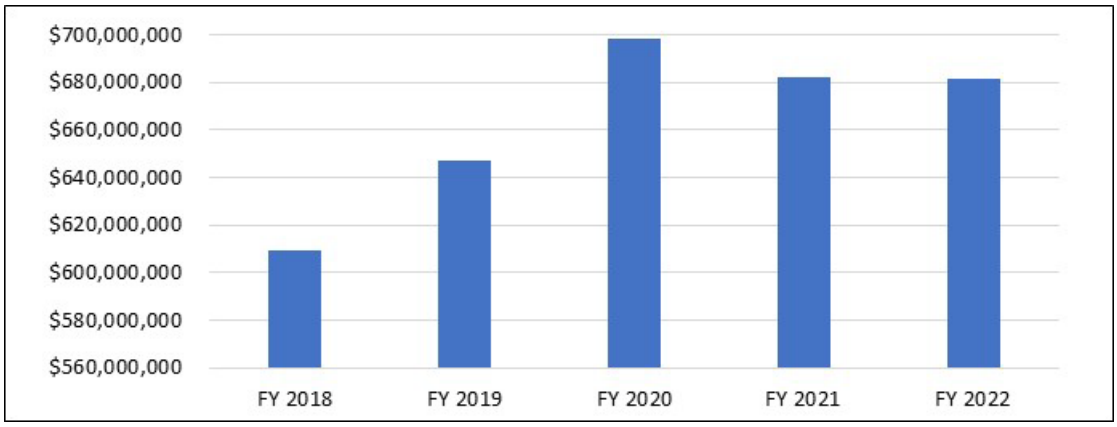
Table 7: GDUFA Program – Historical Trend of Total Costs by Organization as of September 30 for FYs 2018 to 2022

	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CBER Spent ($)	$388,403	$542,786	$869,426	$830,315	$881,356
CBER Percent (%)	0%	0%	0%	0%	0%
CDER Spent ($)	$482,941,769	$526,801,084	$564,114,473	$556,577,415	$547,764,711
CDER Percent (%)	79%	81%	81%	82%	80%
ORA Spent ($)	$82,377,565	$76,818,087	$88,292,430	$79,492,817	$88,908,847
ORA Percent (%)	14%	12%	13%	12%	13%
HQ Spent ($)	$43,821,171	$43,151,434	$44,808,856	$45,015,578	$43,847,098
HQ Percent (%)	7%	7%	6%	7%	6%
Total Spent	**$609,528,908**	**$647,313,391**	**$698,085,185**	**$681,916,125**	**$681,402,012**

Numbers have been rounded to the nearest dollar or nearest percentage.

Exhibit 4 below provides an illustration of historical GDUFA costs.

Exhibit 4: Historical Total Costs by Fiscal Year



After a period of steady increases from year to year, the total cost of the GDUFA program in FY 2022 was flat compared to FY 2021.

K. User Fee Carryover

GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the GDUFA program in future fiscal years.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees and the risk of a lapse in appropriations. For the GDUFA program, FDA considers maintaining a carryover between 8 to 12 weeks as a reasonable range to mitigate these risks.

The net change in carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 1** above.

Table 6 provides the GDUFA carryover at the end of FY 2021 and FY 2022. The financial notes can be found in **Appendix E**.

Table 6: GDUFA Carryover for FYs 2021 and 2022

Carryover	Notes	FY 2021	FY 2022
Total Carryover, End of Year		**$127,223,404**	**$131,211,761**
Future Year Refunds Allowance, Set Aside	Note 7	($4,000,000)	($4,000,000)
Carryover Net of Set Aside, End of Year		**$123,223,404**	**$127,211,761**

Numbers have been rounded to the nearest dollar.

These terms are defined below:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.

- **Future Year Refunds Allowance, Set Aside** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $4,000,000 in fee funds available for obligation is being set aside annually. See **Note 7** for additional details.

- **Carryover Net of Set Aside, End of Year** – This is the total carryover less any carryover funds subject to set asides.

The operations in FY 2022 resulted in a net increase of the carryover of $3,988,357, from $127,223,404 at the end of FY 2021 to $131,211,761 at the end of FY 2022. The increase in carryover in FY 2022 was primarily driven by actual collections being more than estimated in FY 2022.

Tables 7a and **7b** reflects the historic amount of fees collected and the amount obligated during the previous and current reauthorization periods.

Table 9a: Historical Human Generic Drug User Fee Carryover by Reauthorization Period

	Notes	GDUFA I (FY2013 – 2017)
Total Carryover, Beginning of Year		**$0**
Net Collections		$1,581,961,651
Recoveries	Note 2	$6,688,743
Total Obligations		($1,446,238,346)
Total Carryover, End of Year		**$142,412,048**

Numbers have been rounded to the nearest dollar.

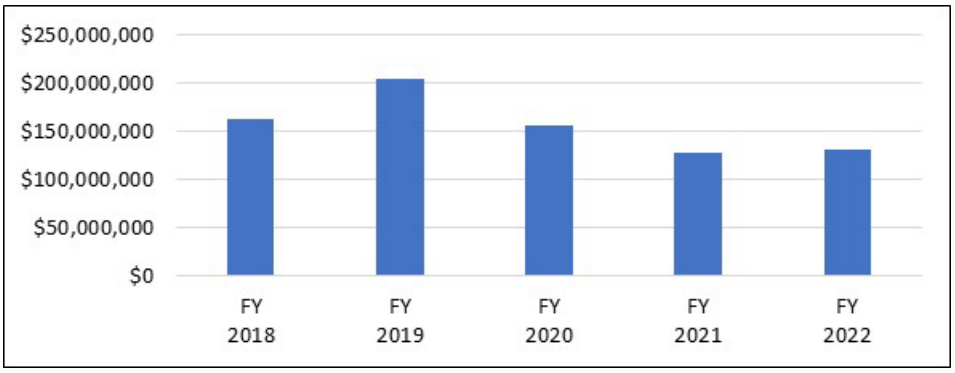
Table 10b: Historical Human Generic Drug User Fee Carryover for the Current Reauthorization Period

	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Total Carryover, Beginning of Year		**$142,412,048**	**$163,715,667**	**$204,171,168**	**$156,731,582**	**$127,223,404**
Net Collections		$493,655,974	$496,503,494	$483,285,782	$500,205,882	$545,842,834
Recoveries	Note 2	$4,920,184	$8,544,957	$9,968,653	$6,535,880	$6,132,460
Total Obligations		($477,272,539)	($464,592,949)	($540,694,021)	($536,249,940)	($547,986,937)
Total Carryover, End of Year		**$163,715,667**	**$204,171,168**	**$156,731,582**	**$127,223,404**	**$131,211,761**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover for the last 5 fiscal years.

Exhibit 5: Historic Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under GDUFA, a certain amount of non-user fee appropriations must be spent on human generic drug activities during that fiscal year. This is often referred to as a "non-user fee spending trigger." The spending trigger was $110,248,454 for FY 2021 and $111,551,649 for FY 2022.

The non-user fee spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on human generic drug activities ($97 million) times the adjustment factor for the fiscal year. See **Note 8** for more details on the adjustment factor.

Table 8 provides the total amount spent on the GDUFA program for the past 5 fiscal years, as well as the dollar amount and percentages derived from user fee and non-user fee appropriations.

Table 8: Historical Generic Drug User Fee Obligations by Funding Source as of September 30 for FYs 2018 to 2022

Funding Source	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Non-User Fee Appropriations Obligated: Total ($)	$132,256,370	$182,720,442	$157,391,163	$145,666,185	$133,415,075
Non-User Fee Appropriations Obligated: Percent (%)	22%	28%	23%	21%	20%
User Fee Funds Obligated: Total ($)	$477,272,539	$464,592,949	$540,694,021	$536,249,940	$547,986,937
User Fee Funds Obligated: Percent (%)	78%	72%	77%	79%	80%
Total Obligated	**$609,528,909**	**$647,313,391**	**$698,085,185**	**$681,916,125**	**$681,402,012**

Numbers have been rounded to the nearest dollar.

M. Full-Time Equivalents

"FTE employment" (often referred to as "staff year"), as defined by Office of Management and Budget (OMB) Circular A-11, section 85, reflects the total number of regular straight-time hours—not including overtime or holiday hours—worked by employees, divided by the number of compensable hours applicable to each fiscal year. Annual leave, sick leave, compensatory time off, and other approved leave categories are considered "hours worked" for purposes of defining FTE employment.

As they relate to GDUFA, FTEs are referred to as "Process FTEs." Process FTEs are how FDA measures a paid staff year devoted to the GDUFA program. In the table below, an FTE does not represent an accounting of individual people, but rather an FTE represents an estimate of labor hours expended on GDUFA activities. Funding is distributed to FDA's Centers based on the workload to support payroll to accomplish the program goals.

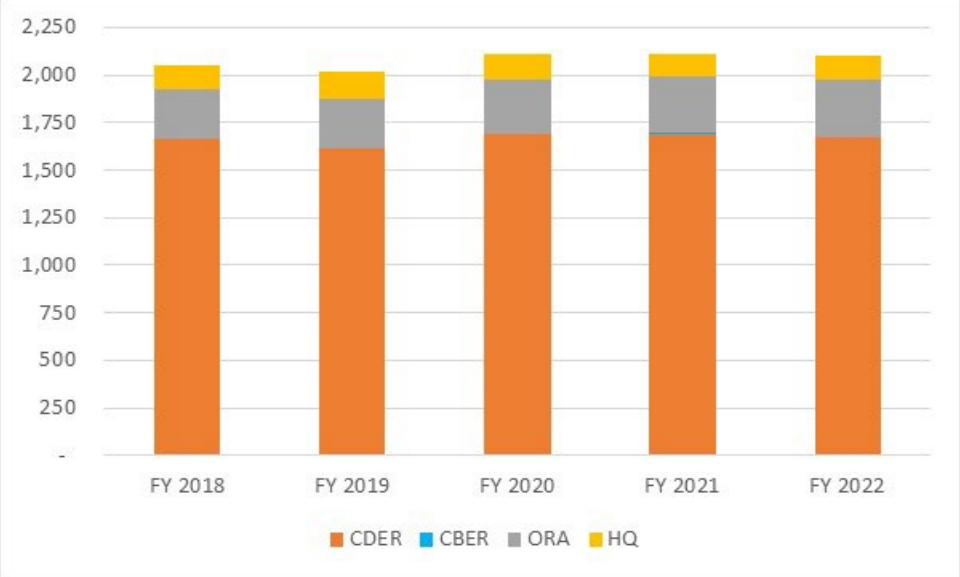
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the GDUFA program. The data covers the past 5 years and is arranged by FDA's organizational components (CDER, CBER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

Table 12: Historical Trend of Total FTEs Utilized by Organization as of September 30 for FYs 2018 to 2022

Organization	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
CBER	1	2	2	2	2
CDER	1,660	1,613	1,689	1,692	1,668
ORA	260	259	288	298	305
HQ	130	141	127	117	123
Total	**2,052**	**2,015**	**2,106**	**2,110**	**2,099**

Exhibit 6 provides the historical trend of FTE distribution and levels across FDA's organizations for the past 5 years.

Exhibit 6: Total FTE Levels by FDA's Organizations



Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular A-123, Management's Responsibility for Enterprise Risk Management and Internal Control, implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

1. Effective and efficient operations,
2. Reliable reporting, and
3. Compliance with applicable laws and regulations.

The Department of Health and Human Services (HHS) provides guidance to its operating divisions (OpDivs) to implement FMFIA through its FMFIA Guidelines. OpDivs, including FDA, are responsible for developing and maintaining internal control and compliance programs that include programmatic and operational controls, as well as reporting controls to support sound financial management. The Government Accountability Office's Standards for Internal Control in the Federal Government (Green Book) states: "Management is responsible for an effective internal control system. As part of this responsibility, management sets the entity's objectives, implements controls, and evaluates the internal control system." OMB Circular A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually on the effectiveness of the internal controls and any identified material weaknesses in those controls.

In alignment with FMFIA, OMB A-123, OMB Circular A-11, the Green Book, and HHS guidelines, FDA established an Enterprise Risk Management (ERM) Program, with an ERM Council as the governance body responsible for providing overall oversight and accountability. The Council's purview includes deciding on and managing the Agency's Enterprise Risk Profile and ensuring integration with FDA's FMFIA, budget formulation, and strategic planning activities. The ERM Council has senior executive representatives from each FDA Center and Office, and is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and Chief Financial Officer (CFO) as President Pro Tempore. FDA's ERM Program supports the Council in managing the Agency's Enterprise Risk Profile, facilitates risk response planning, collaborates with Center and Office senior leaders and staff in conducting a range of analyses to manage risks, and provides communications and training opportunities that promote a risk-informed culture.

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB Circular A-123 assessments, and for fostering an environment that promotes strong internal controls

and reduces the risk of fraud, waste, and abuse. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically:

1. Reporting controls to include business and IT controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk;
2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs;
3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and
4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996.

In FY 2022, FDA's annual assessment of internal controls included tests of 95 business and IT controls across 14 major transaction cycles and 27 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 36 IT controls related to the User Fee System. Further, FDA has enhanced its integration with HHS to focus on IT controls, align with HHS's standardized IT controls guidance, and overall collaborate with HHS (Appendices A and B).

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2022, FDA completed the FDA FY22 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. The FDA Programs – FDA User fees (Non-General Fund), Animal Drugs and Feed, FDA Other Activities (FDA Headquarters), Payment to FDA Innovation Account, National Center for Toxicological Research, Coronavirus Emergency Funding Supplemental and FDA Buildings and Facilities – were deemed to not be susceptible to significant improper payments. The Biologics and Devices & Radiological Health programs were selected for transactional testing (Appendix C).

The Unified Financial Management System FDA-set-of-books and the User Fee System are compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996 (Appendix D).

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data are presented in HHS's consolidated financial statements. The FY 2022 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2022, and 2021, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2022 Assurance Statement found no material weaknesses or financial system nonconformances.

O. Risks and Challenges

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some in FDA's control and some out of FDA's control. An example of a financial risk shared across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can only assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user fee spending trigger for the fiscal year if that total appropriation is considerably lower than anticipated. Below is a list of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans; these contingency plans help ensure FDA is able to move forward in the best interests of the program.

- **Under-Executing Planned Spend:** GDUFA budgetary resources have been under spent due to the uncertainty around the timing of revenue (user fee and non-user fee) availability, non-user fee spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA continued to enhance its planning and execution around the hiring of new staff and contract actions in the fourth year of the reauthorization. FDA predicts that there will be less variance when comparing planned allocations to actual expenditures than FDA has experienced in the past.

- **Uncertainty of Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates planning challenges as non-user fee fund levels are often uncertain for much of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.

- **Lapse in Non-User Fee Appropriations:** FDA is maintaining a certain level of carryover, which can be used to preserve program operations for a limited time in the event of a shutdown. For the GDUFA program, FDA believes it needs roughly 8 to 12 weeks of carryover to help mitigate this risk.

- **Under Collecting and Over Collecting:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in targeted revenue. When FDA under collects user fees, it leverages its carryover to maintain continuity in operations. When FDA over collects, the carryover may increase without additional planned expenditures being identified towards which to obligate those funds. In addition, FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates. Actual collections were slightly above estimated collections in FY 2022.

- **Global Pandemic:** There is some degree of uncertainty regarding the potential long-term impact of COVID-19 on collections and application submissions. FDA is continually monitoring these impacts and will seek to address financial ramifications as warranted.

In addition to these mitigation strategies, FDA implemented the Integrated Budget and Acquisition Planning System (IBAPS) to enable a greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of the Agency's resources.

Strategic Challenges

FDA acknowledges that the anticipated workload is the greatest unknown and most impactful variable throughout GDUFA II. Predicting direct ANDA review work by FDA and industry has been challenging in GDUFA I and II. Moving forward, the addition of the capacity planning adjustment (effective beginning with FY 2024) under GDUFA III should help address this challenge.

Appendices

A. Reporting Requirements

The following table provides details regarding the financial reporting requirements for GDUFA.

Requirement	Details
Title IX, Section 903 of FDARA	The law revises the FD&C Act's requirements for performance reports under user fee provisions for prescription drugs, medical devices, generic drugs, and biosimilars, including to require the quarterly publication of information regarding guidances and meetings. In addition, performance reports must include: (1) an analysis of changes in the number of FTEs hired under user fee agreements and the number funded by budget authority, (2) an analysis of changes in user fee revenue amounts and review costs, and (3) the number of employees in specified FDA offices for whom time reporting is required and the number for whom it is not required.
Section 744C(b) of the FD&C Act	The law requires that a fiscal report, beginning with fiscal year 2018, is submitted no later than 120 days after the end of each fiscal year for which fees are collected. This report should include information on the implementation and use of fees collected that fiscal year.

B. Allowable and Excluded Costs for the GDUFA Program

Section 744A(9) of the FD&C Act defines the term "human generic drug activities," in general, as the activities associated with generic drugs and inspection of facilities associated with generic drugs. In summary, costs related to the following have been attributed to human generic drug activities:

Included Activities

1. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions.
2. The issuance of:
   a. Approval letters that approve ANDAs or prior approval supplements to such applications.
   b. Complete response letters that set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.
3. The issuance of letters related to Type II API DMFs that:
   a. Set forth in detail the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or
   b. Document that no deficiencies need to be addressed.
4. Inspections related to generic drugs.
5. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs.
6. Post-market safety activities with respect to drugs approved under ANDAs or supplements, including the following activities:
   a. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports.
   b. Developing and using improved adverse-event data collection systems, including IT systems.
   c. Developing and using improved analytical tools to assess potential safety problems including access to external databases.
   d. Implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to ANDAs.
   e. Carrying out section 505(k)(5) (relating to adverse-event reports and post-market safety activities).
7. Regulatory science activities related to generic drugs.

Section 744A(12) of the FD&C Act defines the term “resources allocated for human generic drug activities” as expenses for the following:

Included Expenses

1. Officers and employees of FDA, contractors of FDA, advisory committees, and the costs related to such officers, employees, and committees, and to contracts with such contractors.
2. Management of information and the acquisition, maintenance, and repair of computer resources.
3. Leasing, maintenance, renovation, and repair of facilities and acquisition, maintenance and repair of fixtures, furniture, scientific equipment, and other necessary materials and supplies.
4. Collecting fees under section 744B and accounting for resources allocated for the review of ANDAs and supplements and inspection related to generic drugs.

The GDUFA program excludes costs related to the following:

Excluded Activities
1. All activities necessary for the review of new drug applications, biologic license applications, and investigational new drugs for drugs that will not be approved under ANDAs. 2. The issuance of controlled correspondence unrelated to abbreviated new drug submissions, pre-ANDAs, or prior approval supplements. 3. Inspections unrelated to human generic drugs. 4. Monitoring of research unrelated to human generic drug submissions and DMFs. 5. Post-market safety activities apart from those drugs approved under ANDAs or supplements.

C. User Fee Program History

The FD&C Act, as amended by FDARA, authorizes FDA to collect user fees from the generic drug product industry to supplement the non-user fee appropriations that the Agency spends on human generic drug activities. FDA spends fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the generic drug review program to ensure the American public has access to safe, high-quality generic drugs.

Originally authorized in 2012,[5] GDUFA was reauthorized by Congress under FDARA in 2017 (GDUFA II) with the support of the generic drug industry, public stakeholders, and the Administration.

D. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by FDARA, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend generic drug user fees. This appendix describes these conditions and the applicable adjustment factor, as listed in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate an adjustment factor (defined in section 744A(3) of the FD&C Act as amended) in the assessments of the first and third conditions. The FD&C Act states:

[5] See https://www.fda.gov/media/82022/download.

The term “adjustment factor” applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items, United States city average) for October of the preceding fiscal year divided by such Index for October 2011.

The Consumer Price Index (CPI) for October 2020, the October of the fiscal year preceding FY 2022, was 260.388. The CPI for October 2011 was 226.421. Dividing the CPI of October 2020 by the CPI of October 2011 yields an adjustment factor of 1.150017 (rounded to the sixth decimal place) for FY 2022.

Legal Conditions

Exhibit 7 below provides the details regarding each legal condition, as quoted from the FD&C Act.

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	744B(h)(1)	Fees under subsection (a) shall be refunded for a fiscal year beginning after fiscal year 2012, unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for fiscal year 2009 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor (as defined in section 744A) applicable to the fiscal year involved.
2	744B(i)(2)(A)(i)	The fees authorized by this section—(i) subject to subparagraph (C), shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation, for such fiscal year.
3	744B(i)(2)(A)(ii)	The fees authorized by this section— (ii) shall be available for a fiscal year beginning after fiscal year 2012 to defray the costs of human generic drug activities (including such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such activities), only if the Secretary allocates for such purpose an amount for such fiscal year (excluding amounts from fees collected under this section) no less than $97,000,000 multiplied by the adjustment factor defined in section 744A(3) of this title applicable to the fiscal year involved.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

The estimated user fee collections are based on the target revenue (i.e., base revenue adjusted for inflation).

Note 2. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended.

Note 3. Pay and Operating Costs

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support the GDUFA program. If an operating activity solely supports GDUFA, it will be fully funded by the program. If the operating activity is shared, GDUFA will fund the activity in proportion to how it is used by the program as compared to other programs.

Note 4. Rent Costs

The General Services Administration charges rent to FDA for the federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential support cost for human generic drug activities, a portion of those charges is paid from non-user fee appropriations and a portion is paid from GDUFA fees. Also included in this account are recurring costs that FDA pays directly to non-federal sources under the delegation of direct lease and service authority. These services include rental of space, and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent related costs each Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Service Costs

FDA has several shared service organizations, located with the Working Capital Fund, that provide support across the user fee programs. The shared service organizations in FY 2022 include:

- **FDA Central:** Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.

- **Employee Resource & Information Center:** Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services:** Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity, and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Information Management and Technology:** Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote public health.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is comprised of several appropriation accounts including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA's safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.
- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust, and mutual respect.
- **Office of Talent Solutions:** Provides high-quality and efficient human resource solutions that enable FDA to hire a talented and qualified workforce.
- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA's leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

Note 6. Inflation Adjustment

The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the CPI and payroll-related expenses by changes in FDA's average personnel compensation and benefits amounts.

The inflation adjustment utilized in FY 2022 was 2.1451 percent.

Note 7. Future Year Refunds Allowance, Set Aside

If an ANDA is considered not to have been received within the meaning of section 505(j)(5)(A) of the FD&C Act for a cause other than failure to pay user fees, or if the ANDA is withdrawn prior to be being received within the meaning of section 505(j)(5)(A), the applicant is eligible for a 75 percent refund of the ANDA filing fee. If an ANDA is initially received under section 505(j)(5)(A), but FDA subsequently determines that the exclusivity period for a listed drug should have prevented the ANDA from being received, the ANDA is no longer considered received under section 505(j)(5)(A), and the applicant is eligible for a full refund of the ANDA filing fee paid.

Refunds impact net fee collections for each fiscal year. Net collections reflect the amount of fees collected net any refunds or adjustments that occurred during that fiscal year.

Note 8. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate an adjustment factor (defined in section 744A(3) of the FD&C Act, as amended by FDARA). The FD&C Act states, "the term 'adjustment factor' means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011."

Note 9. Final Year Adjustment

Under statutory authority in effect for FY 2022, FDA may, in addition to the inflation adjustment, further increase the fee revenue and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2023. To determine whether a final year adjustment applies, FDA calculated the operating reserves of its carryover and its estimated balance as of the beginning of FY 2023.

After running analyses on the projected collections and obligations for FY 2021 and FY 2022, FDA estimated that the available carryover balance would be $63,131,283 as of the beginning of FY 2023, which represented approximately 6 weeks of operating reserves. Per the statute, FDA could raise the fee revenue by $59,301,948 for the final year adjustment. FDA recognized that adding $59,301,948 to the fee revenue in FY 2022 may pose a burden to the regulated industry. In light of this and the fact that the

legislative language authorizing the final year adjustment allows FDA discretion in whether to make this adjustment for a full 3 months of operating reserves or for a shorter period, FDA decided to make the final year adjustment to allow for only 7 weeks of operating reserves. Accordingly, the final year adjustment was $8,288,102.

This report was prepared by FDA's Office of Financial Management.
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