FY 2019 GDUFA FINANCIAL REPORT

REQUIRED BY THE

GENERIC DRUG USER FEE AMENDMENTS

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Table of Contents

Executive Summary

The Generic Drug User Fee Amendments (GDUFA) require the Food and Drug Administration (FDA or the Agency) to report annually on the financial aspects of GDUFA implementation. Required under GDUFA, this report covers fiscal year (FY) 2019. This is the seventh GDUFA Financial Report, and the second report under the Generic Drug User Fee Amendments of 2017, also known as GDUFA II.

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 2019, 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 balances, as well as comparative data from prior years.

In FY 2019, FDA had net collections of $497 million in human generic drug user fees, spent $465 million in user fees for the human generic drug review process, and carried a cumulative balance of $204 million forward for future fiscal years.

GDUFA user fees and non-user fee appropriations in FY 2019 supported 2,015 full-time equivalents (FTEs), including salaries and operational expenses, to support human generic drug activities. Detailed program accomplishments can be found in the FY 2019 GDUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation and use of human generic drug user fees by FDA during the period of October 1, 2018, through September 30, 2019. It 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 FY 2019 fee collections, carryover balances, obligations of user fees, and total costs of human generic drug activities from both 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 such fiscal year and the use by FDA of the fees collected for such 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 ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation.

FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public's health by helping to speed innovations that make medical products more effective, safer, and more 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 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, 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 minimizing risk 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 Agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This 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's user fee governance process leverages the User Fee Financial Management Committee, which 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 User Fee Financial Management Committee is responsible for providing oversight and support of appropriate standards and policies to ensure FDA compliance with sound financial management practices, as well as compliance with statutory provisions that authorize FDA to collect and spend user fees. The User Fee Financial Management Committee 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 User Fee Financial Management Committee 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 collects fees from human generic drug manufacturers to fund the human generic drug review process. The FD&C Act, as amended by the FDA Reauthorization Act of 2017 (FDARA), authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on human generic drug activities.

FDARA includes GDUFA II, which extends 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 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 (PAS) 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 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, 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 his or her affiliates will be assessed an annual fee depending on the number of approved ANDAs in his or her portfolio.
Facility	*Domestic and Foreign Active Pharmaceutical Ingredients (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 finished dosage forms 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]

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.

[1] See the GDUFA user fee rates archive at *https://www.fda.gov/ForIndustry/UserFees/GenericDrugUserFees/ucm313983.htm*

E. Legal Conditions

The FD&C Act, as amended by FDARA, 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 Legal Conditions

Legal Condition #	Details	
1	Description	The first condition requires that FDA's FY 2019 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 2019 total appropriation for salaries and expenses (excluding user fees) was $3,068,678,000, whereas the FY 2009 salaries and expenses appropriation (excluding user fees) was $2,221,247,382 after applying the FY 2019 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, 2019 (Public Law 116-6), which the President signed on February 15, 2019, made appropriations through September 30, 2019, for the Salaries and Expenses account of FDA. It specified that $501,721,000 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 the GDUFA program. The minimum spending from appropriations is $97,000,000 multiplied by the adjustment factor defined in section 744A(3) applicable to the fiscal year involved.
	Met By	The specified minimum level for FY 2019 is $105,671,800. In FY 2019, FDA obligated $182,720,442, exclusive of user fees, for the GDUFA program. As FDA spent more than the specified minimum amount in FY 2019, 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 continues 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:

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

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

Continued enhancement of business processes to increase first cycle approvals and reduce the time to approval by increasing communication and collaboration between FDA and industry

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

- FDA will continue enhancements to 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. These enhancements will include the development of tools that help improve the quality of submissions and identify, earlier in the process, potential issues that could impact approval of an application.

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

- FDA will work to improve the efficiency of the generic drug development, review, and approval process.
- FDA will continue its efforts to maximize scientific and regulatory clarity with respect to complex drugs.
- FDA will continue 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 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 2019 goals are presented below. Refer to the FY 2019 GDUFA Performance Report for additional details.

In FY 2019, FDA approved 935 ANDAs and tentatively approved 236 ANDAs,[2] the highest number of combined generic drug approvals and tentative approvals in the history of the generic drug program. FDA has set this record for 4 consecutive years. 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, 2019, FDA met 97 percent of the goals of such applications and has not missed a single goal for priority original ANDA submissions with an 8-month goal date.[4] As of September 30, 2019, FDA met 98 percent of the goals pertaining to Prior Approval Supplements (PASs). 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, 2019, FDA has met the goal for 99 percent of all standard controlled correspondence and 98 percent of all complex controlled correspondence.

Under GDUFA II, FDA is taking steps to foster earlier development of guidances, which are intended to share the Agency's thoughts on key aspects that should be addressed in related ANDA submissions. In FY 2019, FDA issued 9 draft guidances and 6 final guidances for industry on topics applicable to multiple products, and 107 new draft guidances and 145 revised draft guidances with product-specific recommendations. FDA also issued four Manuals of Policies and Procedures (MAPPs), engaged in

[2] https://www.fda.gov/drugs/abbreviated-new-drug-application-anda/activities-report-generic-drugs-program-fy-2019-monthly-performance.

[3] The performance numbers provided here are for the FY 2019 receipt cohort. These are preliminary numbers that will be updated in the FY 2020 Congressional 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 (PFC).

outreach efforts to educate and inform industry participants and other stakeholders about GDUFA and the generic drugs program, produced webinars and podcasts, and held six regulatory science public meetings and workshops focusing on complex generic drug development.

Financial Information

This section provides an overview of the program financials for GDUFA for fiscal years 2018 and 2019. These financials include user fee revenue, 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 2018 and FY 2019. The financial notes can be found in **Appendix E.**

Table 1: Human Generic Drug Collections, Obligations, and Carryover for FY 2018 and FY 2019

Budgetary Resources	Notes	FY 2018	FY 2019
Target Revenue	Note 1	**$493,600,000**	**$501,721,000**
Total Carryover, Beginning of Year		$142,412,048	$163,715,667
Net Collections		$493,655,974	$496,503,494
Recoveries	Note 2	$4,920,184	$8,544,957
Total Budgetary Resources		**$640,988,205**	**$668,764,117**

Obligations	Notes	FY 2018	FY 2019
Total Payroll and Operating	Note 3	$397,961,320	$384,721,323
Total Rent	Note 4	$22,019,962	$24,962,969
Total Shared Services	Note 5	$57,291,257	$54,908,657
Total Obligations		**$477,272,539**	**$464,592,949**

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$163,715,667**	**$204,171,168**

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

Budgetary Resources: The Budgetary Resources component of **Table 1** illustrates the sum of available user fee funding (i.e., the existing available carryover balance and additional user fee collections) that was used to fund obligations. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Net collections are the amount collected during the fiscal year, for all cohort years combined (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 are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of a fiscal year remain available to FDA for use in future fiscal years. The unobligated GDUFA funds at the end of each fiscal year are referred to as the "carryover balance" as shown in **Table 1**. 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 performing human generic drug activities under the financial constraints.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for FY 2019. 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 Revenue and Collections Statement for FY 2019

Target Revenue	Notes	FY 2019
Base Amount		$493,600,000
Inflation Adjustment	Note 6	$8,121,201
Target Revenue Total	Note 1	**$501,721,000**

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

The process for setting of the annual target revenue is defined in statute. The base amount for FY 2019 is specified in the statute and then adjusted for inflation.

GDUFA specifies that fees are to be collected for ANDAs, DMFs, facilities, and for 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. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2019, but received in FY 2020, is attributed to FY 2019 collections.

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

Table 3 outlines GDUFA collections by fee source and cohort year (CY). Refer to **Section 0** and **Appendix C** for more background and information regarding this change.

Table 3: Human Generic Drug User Fee Collections by Fee Source for CY 2018 and CY 2019

FEES COLLECTED	CY 2018			CY 2019		
	Estimated†	Actual	% Dif.	Estimated†	Actual	% Diff
Application Fees	$162,888,000	$168,644,366	4%	$165,567,930	$160,389,460	-3%
Human Generic Drug Program Fees	$172,760,000	$144,443,886	-16%	$175,602,350	$178,395,663	2%
Facility Fees	$133,272,000	$147,283,511	11%	$135,464,670	$149,315,961	10%
DMF Fees	$24,680,000	$22,718,775	-8%	$25,086,050	$23,703,419	-6%
Total Collections	**$493,600,000**	**$483,090,538**	**-2%**	**$501,721,000**	**$511,804,503**	**2%**

FEES RECEIVABLE	Actual 2018	Actual 2019
Application Fees	$273,166	$185,775
Human Generic Drug Program Fees	$19,407,649	$4,841,641
Facility Fees	$1,372,283	$1,516,123
DMF Fees	$47,829	$7,184
Total Receivables	**$21,100,927**	**$6,550,723**

Numbers have been rounded to the nearest dollar.
†Estimated values were taken from the Human Generic Drug User Fee Rates for Fiscal Year 2018 and 2019.

J. User Fee Obligations

GDUFA fees may be expended only for costs necessary to support "human generic drug activities," as defined in GDUFA. 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 FY 2018 and FY 2019

User Fee Obligations	Notes	FY 2018	FY 2019
Payroll & Operating	Note 3		
CBER		$49,462	$23,658
CDER		$323,591,582	$316,437,772
ORA		$46,518,651	$40,694,363
HQ		$27,801,624	$27,565,531
Total Rent	Note 4	$22,019,962	$24,962,969
Total Shared Services	Note 5	$57,291,257	$54,908,657
Total Obligations		**$477,272,539**	**$464,592,949**

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 is 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. This includes, 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 that provide support across the user fee programs, such as human resources and IT.

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 for regulatory submissions (e.g., ANDAs, pre-ANDA meeting requests, controlled correspondence). As part of the Pre-ANDA Program, FDA developed and published 252 new and revised product-specific guidances in FY 2019. These product-specific guidances have provided industry with draft recommendations on the design of bioequivalence studies and scientific advice pertaining to finished dosage forms and drug substances (active pharmaceutical ingredients) 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 the peer-reviewed scientific literature, presented and discussed at major medical and scientific meetings, and contribute to general guidance development. Since FY 2013, FDA has awarded 155 research contracts and grants. In FY 2019, 20 new external contracts and grants were awarded in addition to the 25 ongoing projects receiving funding. A complete list of FY 2013 through FY 2019 awards can be found at https://www.fda.gov/drugs/generic-drugs/generic-drugs-priorities-projects.

As part of the GDUFA II commitments, FDA posted its FY 2018 GDUFA Science and Research Outcomes. This website provides a list of all the research outcomes for the fiscal year in one easily accessible place and fulfills the commitment to annually report the extent to which GDUFA regulatory-science funded projects support the development of generic drug products, the generation of evidence needed to support efficient review and timely approval of ANDAs and the evaluation of generic drug equivalence. These outcomes are also included in the FY 2018 GDUFA Science and Research Report. The website and report provide greater public transparency regarding the important work the generic drug program engages in to advance the science of generic drugs and provide generic drug developers, applicants, and FDA reviewers essential tools and information to help expedite the availability of high-quality, lower-cost, safe, and effective generic drugs.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the GDUFA program for the past 5 years. As illustrated by the table, costs have increased over time, but the percentage spent by each FDA organization has remained steady.

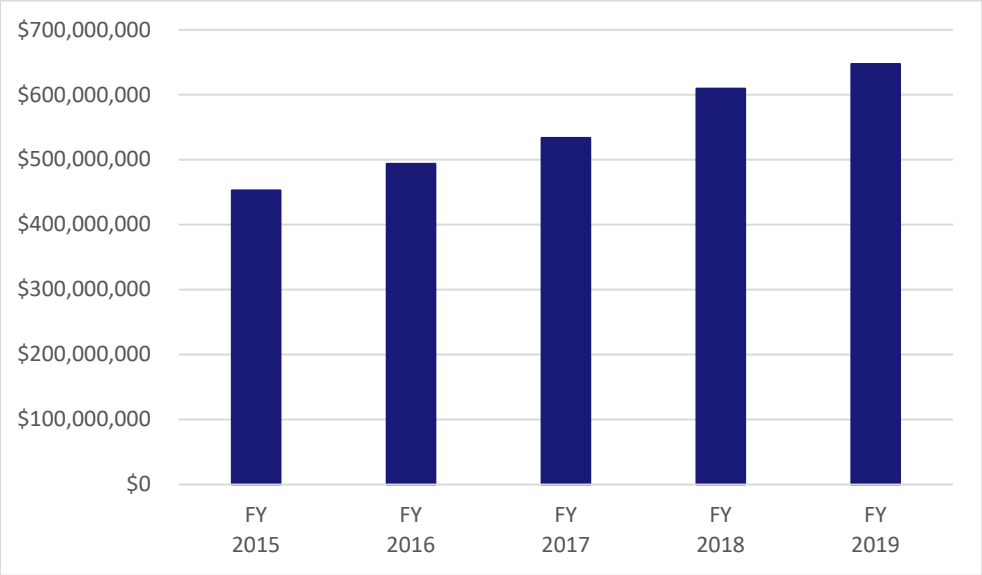
Table 5: GDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Spent		$452,705,318	$493,951,170	$533,807,081	$609,528,908	$647,313,391
CBER	Spent	$547,864	$619,055	$282,889	$388,403	$542,786
	Percent	0%	0%	0%	0%	0%
CDER	Spent	$367,926,837	$398,335,502	$434,049,238	$482,941,769	$526,801,084
	Percent	81%	81%	81%	79%	81%
ORA	Spent	$57,572,841	$62,189,458	$62,508,705	$82,377,565	$76,818,087
	Percent	13%	12%	12%	14%	12%
HQ	Spent	$26,657,776	$32,807,154	$36,966,249	$43,821,171	$43,151,434
	Percent	6%	7%	7%	7%	7%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of historical GDUFA costs.

Exhibit 4: Historic Total Costs by Fiscal Year



As demonstrated by this graph, there has been a steady increase in program expenditures in the past 5 years. In GDUFA I (FY 2013 – FY 2017), the increase was primarily driven by hiring efforts to meet GDUFA goals. While user fee obligations in FY 2019 decreased by about 3 percent from FY 2018, total obligations, inclusive of user fees and budget authority, increased.

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. This balance is referred to as the 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. For the GDUFA program, FDA considers maintaining a carryover balance of between 8 to 10 weeks as a reasonable range to mitigate these risks.

The carryover balance includes 2 categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that preclude FDA from obligating the carryover funds.
- **Carryover Available for Use** – This value represents carryover funds that are not subject to any claims or restrictions and are therefore available for obligation.

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

Table 6 provides the GDUFA carryover balances at the end of FY 2018 and FY 2019. The financial notes can be found in **Appendix E**.

Table 6: GDUFA Carryover for FY 2018 and FY 2019

Carryover	Notes	FY 2018	FY 2019
Total Carryover, End of Year		**$163,715,667**	**$204,171,168**
Refunds	Note 7	($5,000,000)	($5,000,000)
Carryover Unavailable for Use, End of Year		**($5,000,000)**	**($5,000,000)**
Carryover Available for Use, End of Year		**$158,715,667**	**$199,171,168**

Numbers have been rounded to the nearest dollar.

To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Carryover Unavailable for Use, End of Year** – As noted above, this value includes unobligated fee funds subject to any claims or restrictions on fees collected. This includes:
    - **Refunds** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For that purpose, a total of $5,000,000 is being set aside. See **Note 7** for additional details.
- **Carryover Available for Use, End of Year** – As noted above, this is the total carryover less any carryover unavailable for use. These funds become the carryover available for use at the beginning of the next fiscal year.

The operations in FY 2019 resulted in a net increase of the carryover balance of $40,455,501, from $163,715,667 at the end of FY 2018 to $204,171,168 at the end of FY 2019. The increase in carryover balance in FY 2019 was primarily driven by challenges in hiring new staff for the program, underspending in operations, and an increase in available non-user fee appropriations.

Table 7 reflects the historic amount of fees collected and the amount obligated during the previous and current reauthorization periods.

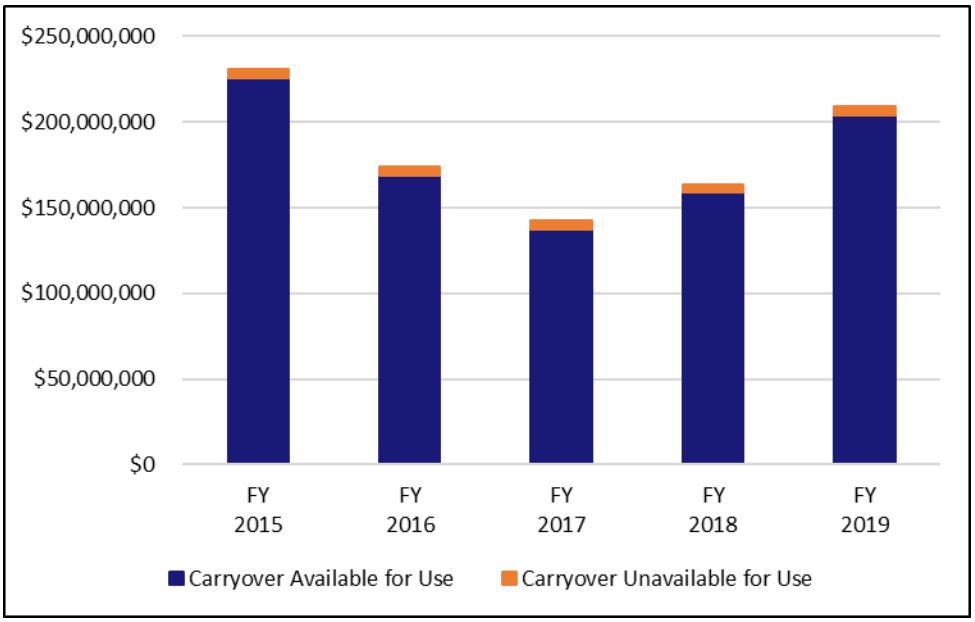
Table 7: Historic Human Generic Drug User Fee Collections, Obligations, and Carryover Balances by Reauthorization Period

Carryover	Notes	GDUFA	GDUFA II	
		FY 2013 – 2017	FY 2018	FY 2019
Total Carryover, Beginning of Year		**$-**	**$142,412,048**	**$163,715,667**
Net Collections		$1,581,961,651	$493,655,974	$496,503,494
Recoveries	Note 2	$6,688,743	$4,920,184	$8,544,957
Total Obligations		($1,446,238,346)	($477,272,539)	($464,592,949)
Total Carryover, End of Year		**$142,412,048**	**$163,715,667**	**$204,171,168**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover for the last 5 fiscal years. As exhibited by the graph, in GDUFA I the carryover trended downward as the program grew and expended more user fees each fiscal year. There is an increase in GDUFA II as noted previously in this section.

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 budget authority (BA) spending trigger." The spending trigger was $103,558,073 for FY 2018 and $105,671,800 for FY 2019.

The non-user fee BA spending trigger amount is determined by multiplying the base amount of non-user fee appropriations spent on human generic drug activities ($97,000,000) 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 years, and the dollar amount and percentages derived from user fee and non-user fee appropriations. CDER identified dollar amounts of the FY 2019 BA initiatives that were included in their base BA budget to support the GDUFA program, which explains the increase in non-user fee appropriation spending in FY 2019.

Table 8: Historical Generic Drug User Fee Obligations by Funding Source as of September 30 of Each Fiscal Year

Obligations		FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
Total Obligated		**$452,705,318**	**$493,951,170**	**$533,807,081**	**$609,528,909**	**$647,313,391**
Non-User Fee Appropriations	Total	$120,624,899	$120,714,671	$140,294,613	$132,256,370	$182,720,442
	Percent	27%	24%	26%	22%	28%
User Fee Revenue	Total	$332,080,419	$373,236,499	$393,512,468	$477,272,539	$464,592,949
	Percent	73%	76%	74%	78%	72%

Numbers have been rounded to the nearest dollar.

M. Full Time Equivalents (FTEs)

FTE employment, or 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 it relates to GDUFA, FTEs are referred to as "Process FTEs." This is 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 estimate of labor hours expended on GDUFA activities. Funding is distributed to FDA Centers based on the workload to support payroll to accomplish the program goals.

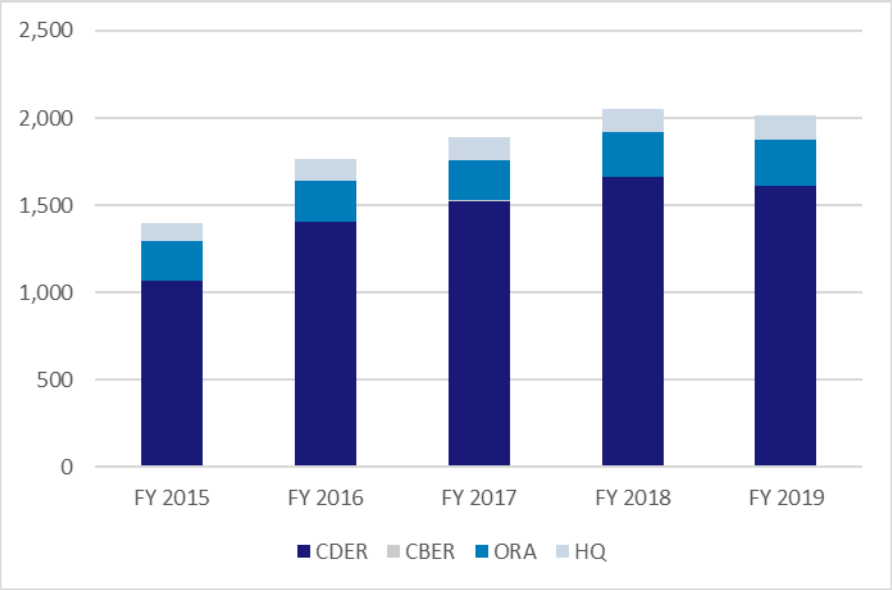
Table 9 presents total Process FTE levels, paid from user fee and non-user fee appropriations, that support the GDUFA program. The data covers the past 5 years and is arranged by FDA organizational components (CDER, CBER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities,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

Table 9: Historical Trend of Total FTEs Utilized by Organization as of September 30 of Each Fiscal Year

Organization	FY 2015	FY 2016	FY 2017	FY 2018	FY 2019
CBER	2	3	1	1	2
CDER	1,064	1,402	1,525	1,660	1,613
ORA	231	238	233	260	259
HQ	100	122	131	130	141
Total	**1,397**	**1,765**	**1,890**	**2,052**	**2,015**

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

Exhibit 6: Total FTE Levels by FDA Organization



Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. OMB Circular No. A-123, *Management's Responsibility for Internal Control and Enterprise Risk Management* (OMB A-123), implements the requirements of the FMFIA. The FMFIA requires that management establish and maintain effective internal control to achieve the objectives of:

1. Effective and efficient operations,
2. Reliable financial 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 a cost-effective internal control and compliance program that includes programmatic and operational controls, as well as controls over financial reporting, and supports sound financial management. The Government Accountability Office (GAO) *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 A-123 requires an annual internal control assessment, and FMFIA requires the head of each executive agency to report annually to the President and Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2019 Assurance Statement, already submitted to HHS, found no material weaknesses or financial system nonconformances.

Additionally, FDA has established a Senior Assessment Team (SAT) as the governance body responsible for providing oversight and accountability for FDA's internal control over financial reporting, including

overseeing the FMFIA and A-123 assessments, and to foster an environment that promotes strong internal control. The SAT is chaired by the FDA Chief Financial Officer (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 appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

In accordance with FMFIA, OMB A-123, the Green Book, and HHS guidelines, FDA has a robust internal control program, including integrated controls throughout processes. The Agency also conducts an annual assessment of its internal control activities as well as operational risk reviews. In addition, FDA has an Enterprise Risk Management (ERM) Program, which began in earnest in FY 2016 and is integrated with FDA's FMFIA efforts. Under the ERM program, FDA has refreshed the enterprise risk profile and facilitated risk response planning for five priority enterprise risks. To accomplish this, Centers and Offices are engaged through senior leadership interviews, as well as working groups and problem-solving sessions. Further, FDA has established an ERM Community of Practice, and continues to align and integrate core ERM methodologies with those of internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks. It is governed by the ERM Council, which is chaired by the Chief Operating Officer and the CDER Deputy Director for Operations.

FDA's internal control program includes an evaluation of controls over reporting, charge card compliance, improper payments, and financial systems compliance. One of the cycle memos included in the assessment scope includes internal controls over reporting for the reimbursable activity process, specifically focused on the Accounts Receivable and Payment process associated with the user fee programs. This includes controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System and the Unified Financial Management System. As an FDA-owned system, FDA's User Fee System is compliant with HHS requirements and requirements of the Federal Financial Management Improvement Act (FFMIA) of 1996. In addition, FDA's Integrated Budget and Acquisition Planning System (IBAPS) meets FDA and HHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of HHS, including the consolidated balance sheet, the related consolidated statement of net costs and changes in net position, the combined statement of budgetary resources, and the related notes to the financial statements. The FY 2019 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of HHS as of September 30, 2019 and 2018, and its consolidated net cost, changes in net position, budgetary resources, and related notes are in accordance with U.S. generally accepted accounting principles.

FDA has also implemented other internal control procedures, including a continuous monitoring program to oversee the timely implementation of corrective action plans for deficiencies identified through any of its control assessments. This continuous monitoring program allows for management oversight of targeted remediation efforts and strengthening of internal controls. In addition, FDA offers annual internal control training sessions, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

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 being in FDA's control and some out of FDA's control. An example of a shared financial risk 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 BA spending trigger for the fiscal year, if that total appropriation comes in considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of funds for which FDA has identified contingency plans in order 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 second year of the reauthorization. By putting more emphasis on the initial planning of initiatives in the early years of the 5-year cycle, FDA predicts that there will be less variance while 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 10 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 balance 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 UFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates. Net collections during GDUFA II have been very close to planned collection (target revenue).

In addition to these mitigation strategies, FDA implemented Integrated Budget and Acquisition Planning System (IBAPS) to enable 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 its resources.

Strategic Challenges

FDA acknowledges that anticipated workload is the greatest unknown and most impactful variable throughout GDUFA II. If industry and FDA can accurately predict ANDA volume, then the financial management of the program will avoid similar challenges it faced in GDUFA I. If, however, the volume of applications is greater than expected, the program will face workload and staffing challenges over the remainder of GDUFA II since FDA does not have a mechanism to increase revenue to keep pace with sustained increases in workload during GDUFA II.

Appendices

A. Reporting Requirements

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

Requirement	Details
FDARA, Title I., Section 303	The law extends through FY 2022 requirements for financial reports and consultation by FDA on reauthorization of generic drug user fees.
FDARA, Title IX, Section 903	The law revises requirements for performance reports under user fee provisions for prescription drugs, medical devices, generic drugs, and biosimilars, including to require quarterly publication of information regarding guidance and meetings. Performance reports must include: (1) an analysis of changes in the number of full time equivalents hired under user fee agreements and the number funded under the FDA budget, (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.
FD&C Act, Section 744C(b)	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 in general, the term "human generic drug activities" 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 which approve ANDAs or prior approval supplements to such applications. b. Complete response letters which 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 active pharmaceutical ingredient DMFs which: 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 abbreviated new drug applications 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 information technology 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 abbreviated new drug applications. 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; and 4. Collecting fees under section 744B and accounting for resources allocated for the review of abbreviated new drug applications 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 (NDAs), biologic license applications (BLAs), and investigational new drugs (INDs) 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, GDUFA was reauthorized by FDARA in 2017 (GDUFA II) with the support of the generic drug industry, public stakeholders, Congress, 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 adjustment factors (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:

> 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 2017, the October of the fiscal year preceding FY 2019, was 246.663. The CPI for October 2011 was 226.421. Dividing the CPI of October 2017 by the CPI of October 2011 yields an adjustment factor of 1.089400 (rounded to the sixth decimal place) for FY 2019.

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

Pay and operating costs associated with the GDUFA program are based on obligations attributed to CBER, CDER, ORA, and HQ. These costs relate to how much of the GDUFA revenue is going toward payroll and operating expenses.

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 number of employees that must be housed.

Note 5. Shared Service Costs

FDA contains several shared service organizations that provide support across the user fee programs. The shared service organizations 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 (ERIC)**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Employee Safety & Environmental Management (ESEM)**: Provides safety, health, and environmental compliance for all FDA employees.
- **Office of Acquisitions and Grants Services (OAGS)**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity (OEEO)**: 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 (OFEMS)**: Provides FDA employees with office and laboratory facilities.
- **Office of Financial Management (OFM):** Provides financial managerial services and policy guidance.
- **Office of Human Resources (OHR)**: Supports workforce relations, client services, executive resources, accountability programs, policy and program development, and systems data and management.
- **Office of Information Management and Technology (OIMT)**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.
- **Alternative Dispute Resolution (ADR):** Provides an alternative resource to existing administrative processes and assists in addressing work-related issues.
- **Division of Budget Execution and Control (DBEC):** Initiates, monitors and analyzes FDA budget resources. The Agency 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.
- **Division of Ethics and Integrity (DEI):** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.

- **Management Analysis Services Staff (MASS):** Provides organizational expertise and policy advice, consultation and support to ensure an efficient Agency structure that delivers on the FDA mission.
- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources, as well as serving as historian for the Agency.
- **Office of Security Operations (OSO):** 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 the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Paperwork Reduction Act (PRA):** FDA's PRA staff acts as the liaison between FDA Centers, HHS, and OMB on all information collection matters.

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 2019 was 1.6453 percent.

Note 7. Refunds

If an ANDA is considered not to have been received within the meaning of FD&C Act section 505(j)(5)(A) 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 adjustment factors (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."