

FIVE-YEAR FINANCIAL PLAN

Fiscal Years
2018-2019-2020-2021-2022
2018 Version

FOR THE

GENERIC DRUG USER FEE AMENDMENTS

PROGRAM

FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES



U.S. FOOD & DRUG
ADMINISTRATION

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Five-Year Plan Overview

A. Scope

The purpose of the Five-Year Financial Plan is to communicate the anticipated financial position of the Generic Drug User Fee Amendments of 2017 (GDUFA II) program over the current five-year authorization period. This document addresses the plan for implementation and use of generic drug user fees by the Food and Drug Administration (FDA or the Agency) during the period of October 1, 2017, through September 30, 2022.

B. Five-Year Plan Commitments

In accordance with *GDUFA Reauthorization Performance Goals and Procedures Fiscal Years FY 2018 Through 2022*, Title VI, Section B, FDA will publish a GDUFA five-year financial plan no later than the second quarter of fiscal year (FY) 2018. FDA will publish updates to the five-year financial plan no later than the second quarter of each subsequent fiscal year. The purpose of this document is to meet these commitments.

C. Updates to the Five-Year Plan

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous year become available. The five-year financial plan provides the baseline from which future changes will be made. Updates to the five-year financial plan will occur on an annual basis, and will only cover the five-years in the current reauthorization period.

Management Discussion

D. 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.

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 current user fee governance process leverages the User Fee Council (UFC) that 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 UFC is responsible for providing oversight support 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. In the near future, FDA expects to make enhancements to its existing governance structure based on recommendations from a third-party evaluation of GDUFA program resource management.

E. User Fee Background and Structure

Under GDUFA, FDA collects user fees from the human generic drug product manufacturers to fund the generic drug product review process. The Federal Food, Drug and Cosmetic (FD&C) Act, as amended by GDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on human generic drug activities.

FDARA includes the reauthorization of GDUFA, also known as GDUFA II, which extends from October 1, 2017 through September 30, 2022. This five-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.

FDA spends GDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of generic drug product applications to help ensure that safe, effective, and high-quality generic drug products are available to the American public.

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 fee until an ANDA is approved.
3. CMOs will pay one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.
4. A firm and its affiliates will pay one 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.
Program	<i>Small</i>	Each company and its affiliates will be assessed an annual fee depending on the number of approved ANDAs in their portfolio.
	<i>Medium</i>	
	<i>Large</i>	
Facility	<i>Domestic Active Pharmaceutical Ingredients (API)</i>	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.
	<i>Foreign API</i>	
	<i>Domestic Finished Dosage Form (FDF)</i>	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.
	<i>Foreign FDF</i>	
	<i>Domestic Contract Manufacturing Organization (CMO)</i>	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.
	<i>Foreign CMO</i>	
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.

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 ([GDUFA User Fee Rates Archive](#)).

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 A** for a detailed list of allowable and excluded activities.

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

F. Five-Year Forward View

Discussion of Workload and Other Activities in GDUFA

GDUFA is a relatively new program having just completed its first authorization period. It faces a high workload and unique programmatic complexities as it continues to mature. GDUFA I was negotiated under the assumption that FDA would receive 750 new original ANDAs each year. In reality, FDA

received an average of approximately 1,000 ANDAs annually throughout GDUFA I. The GDUFA II negotiations assumed 1,000 ANDAs each year. In addition to this increased ANDA volume, the review timeframes in GDUFA II are much more aggressive than in GDUFA I. The estimated increase in workload and the more ambitious goals are the main drivers of the additional funding needs throughout GDUFA II. There exists the potential risk that FDA and industry underestimated the average annual level of ANDA submissions to be received in GDUFA II. A higher number of ANDAs than estimated would require the consumption of additional resources above the planned levels.

FDA is also unable to foresee some trends in the generic drug industry. For example, a great deal of manufacturing has moved overseas in the past few years which has resulted in the need for FDA to conduct more foreign inspections which tend to be more expensive. That expense is offset by the foreign fee differential that overseas manufacturing facilities pay. However, other unpredictable trends in the market could likewise impact FDA's resource consumption.

There are also program enhancements that require increased resources. For instance, there is a new program for complex generic drugs in which FDA provides additional support to applicants in preparing an approvable ANDA. Additionally, CDER's Office of Pharmaceutical Quality (OPQ) conducts research and testing on complex generic drugs to develop a lifecycle research paradigm to pro-actively identify scientific and technical review challenges posed by complex drug products. This helps reviewers evaluate ANDAs more efficiently by establishing clear standards and methods, improving OPQ's readiness to evaluate applications. There are also other enhancements needed such as OPQ's development of the Knowledge-Aided Assessment & Structured Application (KASA) platform which will enhance lifecycle management of drug products.

The 21st Century Cures Act provides new authority to help FDA improve its ability to recruit and retain scientific, technical, and professional experts. This new authority grants FDA the ability to bring on top scientific talent to its review programs at competitive salaries. At this time, FDA does not anticipate the implementation of the 21st Century Cures pay authority will create additional payroll obligations to the process of reviewing human generic drug applications.

FDA is focused on building staff capacity to manage the increasing program workload, meet performance goals, and deliver on new commitments funded in GDUFA II.

Efforts to Enhance Financial Management

GDUFA I was a \$1,500,000,000 agreement covering five years. During the first two years of GDUFA I, as the program was being built, FDA spent significantly less than it collected. Therefore, the carryover balance grew quickly. Eventually, as the program matured, FDA's spending levels increased to exceed its annual collections amounts. Part of the increased spending was due to bringing on term-employees to manage the high pending workload. FDA enters GDUFA II with a carryover balance from GDUFA I, but expects obligations and collections to even out over the course of the next five years.

At the end of FY 2017, the carryover balance was \$142,412,048 which would roughly provide for approximately 15 weeks of operations. FDA considers a carryover level to provide for between 8 – 10 weeks as a reasonable amount of carryover to maintain for the GDUFA program. This level of carryover would provide FDA with sufficient reserves to mitigate possible financial risks to the program, such as under collections or a lapse in appropriations.

FDA plans to reduce this carryover balance to bring it within the 8 – 10-week range by the conclusion of GDUFA II. It plans on accomplishing this primarily through the hiring of term employees. This will provide additional resources to the program to help account for the unexpectedly high submissions levels, while utilizing the reserves available to it. The use of term employees, primarily planned to be

utilized across FY 2019 – FY 2022, will enable the program to utilize these resources to provide necessary support to the program during GDUFA II without creating a long-term payroll liability that might result in a structural deficit (i.e., increasing obligations levels beyond what can be sustained through expected fee revenues) entering GDUFA III. The current plan envisions utilizing approximately \$17,000,000 per year to support these term positions across FY 2019 – FY 2022.

Under GDUFA II, FDA also made commitments to establish a resource capacity planning function and to modernize its time reporting approach. While it will take a number of years to establish and mature the resource capacity planning capability, it will provide the ability to better forecast workload and to translate forecasts into human resource and financial requirements. This capability will help FDA ensure it is optimally deploying the resources available to the GDUFA program.

FDA also made commitments in GDUFA II to help enhance efficiency and transparency in the administration of GDUFA financial resources. This includes a third-party evaluation of GDUFA program resource management during FY 2018 (currently in progress). It also includes the publishing of a five-year plan (this plan), to be updated annually. FDA will also hold an annual public meeting, the first to occur during FY 2019, to discuss this five-year financial plan, along with the agency's progress in implementing resource capacity planning, modernized time reporting, and the impact of the modernized user fee structure

Working Capital Fund/Cost Allocation

FDA has stood up a Cost Allocation and Recovery framework to improve financial management of resources, including GDUFA, the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA). Congress recently passed P.L. 115-141 which provides FDA with the authority to establish a Working Capital Fund (WCF) to finance Agency-wide centralized administrative services. Cost Allocation and Recovery and the WCF will benefit the financial management of Agency user fee funds by:

- Increasing transparency by defining administrative activities performed for Centers and Offices and allocating user fee costs based on Agency usage.
- Strengthening accountability by helping the Agency improve the tracking and management of administrative costs, including costs charged to user fees relative to administrative services.
- Promoting efficiency by optimizing customer usage and improving the management of user fee administrative costs over time.
- Leveraging the WCF governance structure to ensure FDA leadership engagement in decision making relative to administrative costs, efficiency opportunities, recapitalization, and burden on all funding sources – including user fees.

In addition, the WCF authority would enhance efficient use of Agency user fees by specifying the collections that the Agency is authorized to credit to the fund and defining the fund's authorized uses, including which funds may be expended (i.e., scope of services).

Financial Information

This section provides an overview of the projected financial outlook for GDUFA through the fiscal year 2018 – 2022 reauthorization period. These projections include user fee revenue, obligations, carryover, non-user fee appropriations requirements, and planned hiring. The forecasts included in this section are driven by the initiatives and goals as outlined in the Five-Year Forward View section of this plan.

G. User Fee Program Financials

Table 1 represents a summary of the forecasted GDUFA financial position, as it relates to user fee resources (collections and carryover). This table also provides an overview of planned obligations for which the user fee resources would be used. Future updates to this plan will supplement the financial estimates with actual amounts received, obligated, and carried over for the past fiscal year. The financial notes can be found in **Appendix C**.

Table 1: Human Generic Drug Collections, Obligations, and Carryover for Fiscal Year 2018 through Fiscal Year 2022

Budgetary Resources	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	Note 1	\$493,600,000 [†]	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000
Cash Collections		\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000
Carryover Available for Use, Beginning of Year		\$137,412,048 [†]	\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521
Total Cash Available for Obligation		\$631,012,048	\$652,632,425	\$643,354,387	\$640,738,168	\$640,122,521

Obligations	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Payroll and Operating	Note 2	\$410,730,855	\$450,912,792	\$453,725,391	\$461,395,060	\$469,199,094
Total Rent	Note 3	\$25,539,705	\$25,795,102	\$26,053,053	\$26,313,583	\$26,576,719
Total FDA Central	Note 4	\$19,837,301	\$20,035,674	\$20,236,031	\$20,438,391	\$20,642,775
Total Shared Services	Note 5	\$25,670,762	\$25,927,470	\$26,186,744	\$26,448,612	\$26,713,098
Total Obligations		\$481,778,623	\$522,671,038	\$526,201,220	\$534,595,646	\$543,131,686

Carryover	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		\$154,233,425	\$134,961,387	\$122,153,168	\$111,142,521	\$101,990,835
Carryover Unavailable for Use, End of Year		(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)
Carryover Available for Use, End of Year		\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521	\$96,990,835

Target Revenue has been rounded to the nearest thousand dollars

†Indicates an actual amount

Budgetary Resources: The Budgetary Resources component of **Table 1** illustrates the forecast for the sum of available user fee funding (i.e., the existing available carryover balance and additional projected user fee collections) that will be used to fund obligations. The target revenue is the annual revenue amount established when fees for the fiscal year are set. Cash collections is the actual amount collected during the fiscal year. Cash collections is forecasted to be equal to the target revenue, and will be updated with actuals each year.

GDUFA II specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation.

Obligations: The obligations component of **Table 1** shows the planned annual expenditure of GDUFA fee funds broken out into major expense categories.

GDUFA fees may be expended only for costs to support the “human generic drug activities,” as defined in GDUFA II.

Carryover: GDUFA fees are available until expended. This means that the fees that are collected, appropriated, and not obligated at the end of the fiscal year remain available to FDA for use in future fiscal years. The unobligated fee funds at the end of each fiscal year are referred to as the “carryover balance.” Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including for example, the risk of under collecting of fee amounts and the risk of a lapse in appropriations.

H. User Fee Revenue

Table 2 outlines the estimated annual target revenue amounts for each fiscal year. The financial notes referenced in this table can be found in **Appendix C**.

FDA assumes, for planning purposes, that cash collections will equal the target revenue amount. Cash collection 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.

Annual updates to this plan will update the actual target revenue amounts for the current fiscal year and the actual collections amount from the preceding fiscal year.

Table 2: Human Generic Drug Revenue and Collections Statement for Fiscal Year 2018 through Fiscal Year 2022

Target Revenue	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Actual	Estimate	Estimate	Estimate	Estimate
Base Amount		\$493,600,000	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000
Inflation Adjustment		\$ -	\$9,799,000	\$9,994,000	\$10,192,000	\$10,395,000
Target Revenue Total	Note 1	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000

Base Amount and Target Revenue numbers have been rounded to the nearest thousand dollars

Budgetary Resources	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Cash Collections		\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000
Carryover Available for Use, Beginning of Year		\$137,412,048 [†]	\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521
Total Cash Available for Obligation		\$631,012,048	\$652,632,425	\$643,354,387	\$640,738,168	\$640,122,521

[†]Indicates an actual amount

The process for setting of the annual target revenue is defined in statute. Each year’s base amount is to be adjusted for inflation, as described below:

- 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 Consumer Price Index (CPI) and payroll-related expenses by changes in FDA’s average personnel compensation and benefits amounts.

The inflation adjustment for future years, for the purposes of this plan, is estimated by using the Federal Reserve Bank of Cleveland’s CPI projections, as well as historical averages of the changes in FDA’s average salary and benefits amounts.

There was not an inflation adjustment utilized in FY 2018. The average inflation adjustment for FY 2019 – FY 2022 is estimated at 1.9853%.

Unlike PDUFA or BsUFA, GDUFA does not provide for a capacity planning adjustment to adjust the annual target revenue based on changes in workload. As such, increases in ANDAs will lead to a lower fee amount in future years, while FDA will be expected to maintain the same level of performance at the higher workload level, without a commensurate increase in fee revenues.

The base amount for FY 2018 is specified in statute. The base amount for each subsequent year is equal to the prior year’s base plus inflation.

Fee rates are established each year so that revenues from ANDA fees provide 33% of the total revenue, DMF fees provide 5% of the total revenue, FDF and CMO facility fees provide 20% of the total revenue, API facility fees provide 7% of the total revenue and GDUFA program fees provide 35% of the total revenue and support the collection of the target revenue. **Table 3** presents the forecasted total annual collections by fee type.

Table 3: Forecasted GDUFA II Collections

Fee Type	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
ANDA Fees	\$162,888,000	\$166,121,670	\$169,419,690	\$172,783,050	\$176,213,400
DMF Fees	\$24,680,000	\$25,169,950	\$25,669,650	\$26,179,250	\$26,699,000
FDF and CMO Facility Fees	\$98,720,000	\$100,679,800	\$102,678,600	\$104,717,000	\$106,796,000
API Facility Fees	\$34,552,000	\$35,237,930	\$35,937,510	\$36,650,950	\$37,378,600
Program Fees	\$172,760,000	\$176,189,650	\$179,687,550	\$183,254,750	\$186,893,000
Total Cash Collections	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000

Numbers have been rounded to the nearest hundred dollars

I. User Fee Obligations

Table 4 provides a breakout of planned user fee obligations by expense category for the five years represented in this plan. The annual updates to this plan will provide actual amounts for the preceding fiscal year, as well as updated planned amounts for the remaining fiscal years. The financial notes can be found in **Appendix C**.

Table 4: Human Generic Drug User Fee Obligations by Expense Category for Fiscal Year 2018 through Fiscal Year 2022

User Fee Obligations	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Cash Available for Obligation		\$631,012,048	\$652,632,425	\$643,354,387	\$640,738,168	\$640,122,521
Payroll & Operating	Note 2					
CBER		\$966,443	\$982,409	\$999,005	\$1,015,892	\$1,033,075
CDER		\$317,087,240	\$355,752,990	\$361,762,904	\$367,878,059	\$374,100,347
ORA		\$47,066,994	\$47,844,559	\$48,652,821	\$49,475,237	\$50,312,061
HQ		\$45,610,178	\$46,332,834	\$42,310,661	\$43,025,871	\$43,753,610
Total Rent	Note 3	\$25,539,705	\$25,795,102	\$26,053,053	\$26,313,583	\$26,576,719
Total FDA Central	Note 4	\$19,837,301	\$20,035,674	\$20,236,031	\$20,438,391	\$20,642,775
Total Shared Services	Note 5	\$25,670,762	\$25,927,470	\$26,186,744	\$26,448,612	\$26,713,098
Total Obligations		\$481,778,623	\$522,671,038	\$526,201,220	\$534,595,646	\$543,131,686

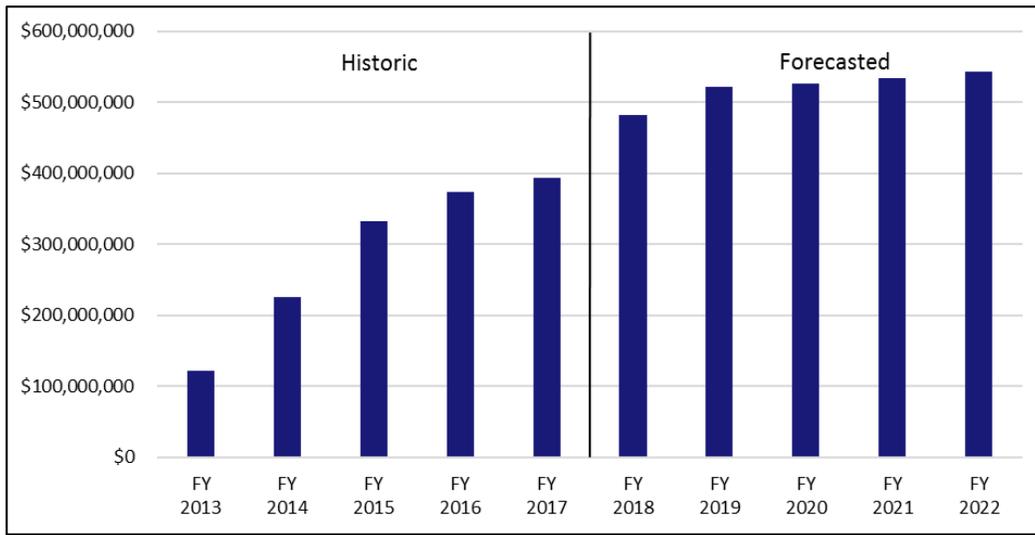
Total obligations include payroll and operating, rent, central, and shared services costs. The details of each component of total obligations is as follows:

- **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 statute. This includes, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, science and research activities, and management and administrative functions that support the GDUFA program.
- **Rent:** This is paid to the General Services Administrations for the Federal buildings that FDA occupies, as well as directly to non-Federal sources for direct leases and services. This rent is charged at different rates depending on the type and location of the space provided.
- **Central:** The Central Account pays for Center-wide and Agency-wide services such as telecommunications, training, printing, mail, and document management, information technology (IT) systems including maintenance, employee health units, and other support and miscellaneous services.
- **Shared Services:** FDA contains a number of shared service organizations that provide support across the user fee programs, such as human resources and IT.

Rent, FDA Central, and Shared Services projections are informed by prior year actuals. The future year amounts, for the purposes of this plan, are assumed to have an increase of 1% yearly. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously.

For historical context, the **Exhibit 3** provides an illustration of historical GDUFA I obligations and projected GDUFA II needs.

Exhibit 3: Historic and Forecasted User Fee Obligations by Fiscal Year



As demonstrated by this graph, there has been a steady increase in user fee expenditures in the past five years. This increase in needs is primarily driven by a greater than expected volume of ANDA submissions and associated workload along with program enhancements, and inflation.

For FY 2018 through FY 2022, FDA assumes the program spending will increase as the carryover balance diminishes.

J. 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 of fee amounts and the risk of a lapse in appropriations. For the GDUFA program, FDA considers an amount equivalent to between 8-10 weeks of operations to be a reasonable amount of carryover.

FDA recognizes that the projected end of FY 2018 carryover is greater than the amount it considers to be reasonable and FDA plans to reduce the carryover amount during the years FY 2019 – FY 2022 as discussed in the Five Year Forward View section of this plan.

The carryover balance includes two categories:

- **Carryover Unavailable for Use** – This value represents carryover funds subject to claims or restrictions that precludes 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 5 provides projections of GDUFA carryover balances at the end of each fiscal year. Forecasted estimates will be updated with actual amounts in future Five-Year Financial Plan annual updates. The financial notes can be found in **Appendix C**.

Table 5: GDUFA Carryover by Fiscal Year

Carryover	Notes	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
		Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year		\$154,233,425	\$134,961,387	\$122,153,168	\$111,142,521	\$101,990,835
Refunds	Note 6	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)
Carryover Available for Use, End of Year		\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521	\$96,990,835

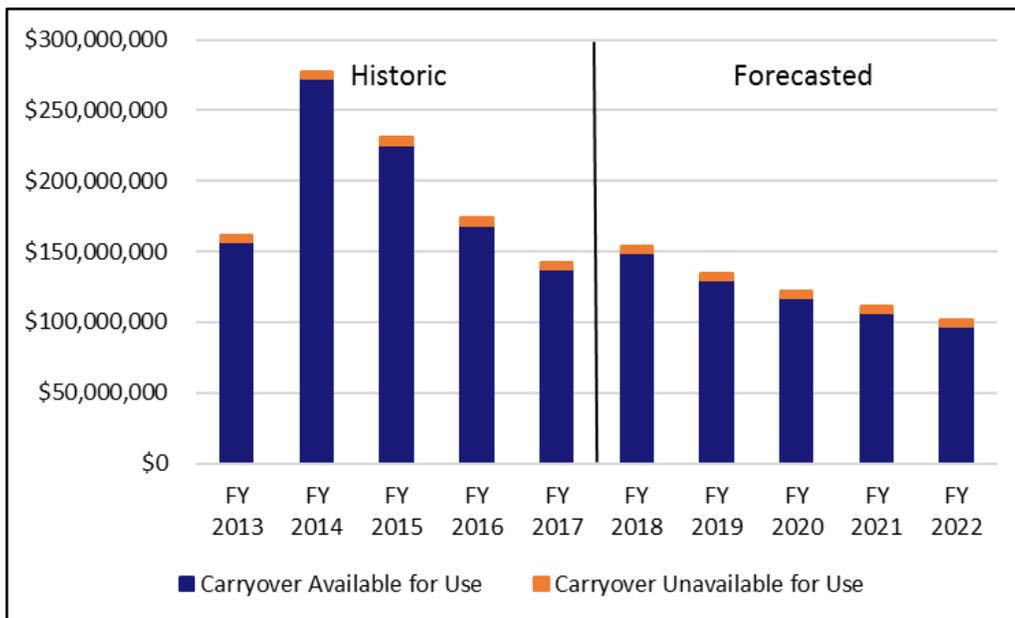
To determine how much carryover is available for obligation at the end of a fiscal year, the following factors must be considered:

- **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 6** 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.

For the purposes of this plan, future year recoveries have not been estimated. Additional details on recoveries are included in **Note 8**.

Exhibit 4 below shows the historic trend of carryover in GDUFA II and the forecasted carryover in GDUFA II.

Exhibit 4: Historic and Forecasted Carryover by Fiscal Year



As illustrated, FDA plans to reduce the amount of carryover in GDUFA II.

Target revenue and forecasted obligations take into account the program needs for each year, and are calculated to increase from the end of FY 2018 to the end of FY 2022.

Carryover Reduction
Available carryover is expected to be reduced from \$149,233,425 in FY 2018 to \$96,990,835 in FY 2022. That is a reduction of 35% over the course of GDUFA II.

K. 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”. **Table 6** presents the forecasted non-user fee BA spending trigger for GDUFA II.

Table 6: Minimum Allocation of GDUFA Non-User Fee Appropriations by Fiscal Year

FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
Actual	Estimate	Estimate	Estimate	Estimate
\$103,558,073	\$105,671,800	\$107,040,373	\$108,497,604	\$109,909,051

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 9** for more details on the adjustment factor.

FDA plans to spend at least the required minimum from non-user fee appropriations each fiscal year. In years when FDA programs do not receive appropriations to cover costs of inflation and mandatory pay increases, other FDA activities other than generic drug review may be reduced to assure that the allocation of non-user fee appropriations for generic drug reviews meets the requirements of this trigger.

L. Planned Hiring

FDA acknowledges that there is carryover and is finalizing the details on the best use of the carryover balance including hiring additional term limited employees. Future versions of this plan will provide updates on this initiative.

Management Assurance

M. Internal Controls

The Federal Managers’ Financial Integrity Act (FMFIA) of 1982 is intended to strengthen internal controls and accounting systems. The Office of Management and Budget’s 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.

DHHS 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) state, "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 the Congress on the effectiveness of the internal controls and any identified material weaknesses in those controls. FDA's FY 2017 Assurance Statement that was submitted to DHHS, 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 the HHS Guidelines, FDA has a robust internal control program, including integrated controls throughout processes, and conducts an annual assessment of its internal control activities. 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 5 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 piloted integration with internal controls. FDA's ERM program has facilitated cross-Center and Office collaboration to identify and manage risks.

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, 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 DHHS system requirements.

FDA is also a participant in the annual audit of the consolidated financial statements of DHHS, including the consolidated balance sheets, 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 2017 audit found that the financial statements present fairly, in all material respects, the consolidated financial position of DHHS as of September 30, 2017 and 2016, and its consolidated net cost, changes in net position, and budgetary resources for the years then ended 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 any Corrective Action Plans (CAPs) 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 annually, which cover the importance of internal controls, timely deficiency remediation, and roles and responsibilities.

N. 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 interest of the program.

- **Under-Executing Planned Spend:** To minimize the risk of under-spending, FDA is enhancing its planning and execution around the hiring of new staff and contract actions in this first year of the reauthorization. By putting more emphasis on the initial planning of initiatives in the first year of the five-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 User Fee Council and other FDA senior leaders determine how to mitigate any instances when user fee revenue strays from forecasted estimates.

In addition to these mitigation strategies, FDA implemented the 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, applications are greater than expected, the program will face workload and staffing challenges over the next five years since FDA does not have a mechanism to increase revenue to keep pace with sustained increases in workload during GDUFA II.

Appendices

A. 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
<ol style="list-style-type: none"> 1. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions. 2. The issuance of— <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 6. Post-market safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities: <ol style="list-style-type: none"> 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
<ol style="list-style-type: none"> 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 744H and accounting for resources.

The GDUFA program excludes costs related to the following:

Excluded Activities
<ol style="list-style-type: none"> 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 correspondence unrelated to abbreviated new drug submissions 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.

B. User Fee Program History

The FD&C Act, as amended by GDUFA, authorizes FDA to collect user fees from the generic drug product industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of generic drug applications and inspecting facilities. 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 and high quality generic drugs and generic drug products.

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.

C. Financial Notes

Note 1. Annual Target Revenue Methodology

The estimated user fee collections over the five-year period represented by this plan are based on the target revenue (i.e., base revenue adjusted for inflation).

Note 2. 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 A** 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 3. Rent Costs

The General Services Administration (GSA) 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 the process for the review of human drug applications, 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 4. FDA Central Costs

The Central Account pays 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. Like rent, the amount of central account support FDA pays is directly related to the number of employees that must be serviced. Each Center pays its portion based on the number of employees working in the GDUFA program.

Note 5. Shared Service Costs

FDA contains a number of shared service organizations that provide support across the user fee programs. The shared service organizations include:

- **Employee Resource & Information Center (ERIC):** Provides support to all FDA users 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 External Affairs (OEA):** Provides the development, coordination and dissemination of FDA communications and outreach to the news media and various stakeholders.
- **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.

Note 6. Refunds

If an ANDA is considered not to have been received within the meaning of section 355(j)(5)(A) for a cause other than failure to pay user fees, or if the ANDA is withdrawn prior to being received within the meaning of section 355(j)(5)(A), the applicant is eligible for a 75% refund of the ANDA filing fee. If an ANDA is initially received under section 355(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 355(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 7. Final Year Adjustment

For FY 2022, the Secretary may, in addition to the inflation adjustment, further increase the fee revenues and fees established if such an adjustment is necessary to provide for not more than three months of operating reserves of carryover user fees for human generic drug activities for the first three months of FY 2023. If such an adjustment is necessary, the rationale for the amount of the increase shall be contained in the annual notice establishing fee revenues and fees for FY 2022.

Note 8. Recoveries

Recoveries account for funds returned to the Agency in the form of deobligations of prior year obligations.

Note 9. 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 GDUFA). 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.”