Financial Report to Congress

Over-the-Counter Monograph Drug User Fee Program

FY 2023

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Executive Summary

On March 27, 2020, new provisions were added to the Federal Food, Drug, and Cosmetic Act (FD&C Act) by the Coronavirus Aid, Relief, and Economic Security Act (CARES Act), which authorize the Food and Drug Administration (FDA) to assess and collect user fees from qualifying manufacturers of over-the-counter (OTC) monograph drugs and submitters of OTC monograph order requests (OMORs). Section 744N(b) of the FD&C Act requires FDA to report annually on the financial aspects of its implementation of authority for the OTC monograph drug user fee program(referred to as "OMUFA"). This is the third OMUFA financial report and covers fiscal year (FY) 2023.

Section 744M of the FD&C Act, as added by the CARES Act, specifies that the following two legal conditions must be satisfied each fiscal year for FDA to collect and spend OMUFA user fees:

1. The fees must be appropriated before they can be collected and available for obligation; and
2. FDA must allocate for OTC monograph drug activities a minimum of $12 million of appropriations (excluding user fees) multiplied by an adjustment factor.

FDA met the two legal conditions in FY 2023, and this report explains how these legal conditions were satisfied. In addition, the statements and tables in the report provide data on OTC monograph drug user fee collections, expenditures, and carryover.

In FY 2023, FDA had net collections of $27 million in OTC monograph drug user fees, spent $26 million in user fees for OTC monograph drug activities, and carried $22 million forward for future fiscal years.

OMUFA user fees and non-user-fee appropriations in FY 2023 supported 196 full-time equivalents, including salaries and operational expenses, to support OTC monograph drug activities. Detailed program accomplishments can be found in the FY 2023 OMUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation of the Over-The-Counter Monograph Drug User Fee Program (referred to as "OMUFA") and the use of OMUFA fees by the Food and Drug Administration (FDA or Agency) during fiscal year (FY) 2023 (i.e., from October 1, 2022, through September 30, 2023). This report presents the legal conditions that FDA must satisfy to collect and spend OMUFA fees each fiscal year and documents how FDA determined that it had met those requirements. In addition, this report presents summary statements of FY 2023 fee collections, carryover, obligations of user fees, and total costs of over-the-counter (OTC) monograph drug activities covered by OMUFA fees and non-user-fee appropriations.

B. Report Requirements

In accordance with section 744N(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 OMUFA fees during each fiscal year and the use by FDA of the fees collected for each fiscal year. The purpose of this report is to meet these requirements.

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

C. Organization Background

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

Program Organization

There are three major FDA components that support the OMUFA program: the Center for Drug Evaluation and Research (CDER), 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.
ORA	Protects consumers and enhances public health by maximizing compliance of FDA-regulated products and minimizing the 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 the Agency's performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This governance includes an understanding of the design of these programs, clear financial plans, data-driven

decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

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

D. User Fee Background and Structure

Section 744M of the FD&C Act (21 U.S.C. 379j-72) authorizes FDA to assess and collect: (1) facility fees from qualifying owners of OTC monograph drug facilities and (2) fees from submitters of qualifying OTC monograph order requests (OMORs). These fees are to support FDA's OTC monograph drug activities, which are detailed in section 744L(6) of the FD&C Act and include various FDA activities associated with OTC monograph drugs and inspection of facilities associated with such products.

Section 744M of the FD&C Act authorizes the OMUFA program from FY 2021 through FY 2025. This 5-year authorization provides for user fee funding to support FDA's monograph drug activities. FDA anticipates that this user fee program will provide resources to help the Agency conduct these important regulatory activities in a timely manner and ultimately help provide the public with increased access to innovative OTC monograph drugs.

Exhibit 2 outlines the OMUFA user fee structure.

Exhibit 2: OMUFA's Fee Structure

Fee Type		Definition
Facility	*OTC Monograph Drug Facility (MDF)*	An MDF fee is owed by each person that owns a facility identified as an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period. An MDF fee applies to each such facility owned by the person.
	Contract Manufacturing Organization (CMO)	A CMO fee is owed by each person that owns an OTC monograph drug facility on December 31 of the fiscal year or at any time during the preceding 12-month period, where neither the owner nor any affiliate of the owner sells the OTC monograph drug produced at such facility directly to wholesalers, retailers, or consumers in the United States. A CMO fee applies to each such facility owned by the person. The CMO fee is two-thirds the MDF fee.
Over-the-counter monograph order request (OMOR)	*Tier 1 and Tier 2*	An OMOR fee is generally assessed to each person who submits an OMOR (other than certain safety-related OMORs). A Tier 1 OTC monograph order request means any OTC monograph order request not determined to be a Tier 2 OTC monograph order request. Tier 2 OTC monograph order requests include a defined limited set of types of requests that are expected to require fewer FDA resources than Tier 1 OTC monograph requests.

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments to facility fees made for inflation (after FY 2021), additional dollar amounts, additional direct costs, and the operating reserve. The fee amounts for each fiscal year are to be published in the *Federal Register*.[1]

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

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

E. Legal Conditions

Sections 744M(f)(1) and (f)(2)(B) of the FD&C Act, respectively, specify two legal conditions that must be satisfied each year for FDA to collect and spend OTC monograph drug user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met.

[1] See the OMUFA user fee rates at https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-user-fee-program-omufa.

Exhibit 3: OMUFA's Legal Conditions

Legal Condition #	Details	
1	Description	Fees shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.
	Met By	The Agriculture, Rural Development, Food and Drug Administration, and Related Agencies Appropriations Act (Division A of the Consolidated Appropriations Act, 2023 (Public Law 117-328), which the President signed on December 29, 2022, specified that fees relating to OTC monograph drugs authorized by 21 U.S.C. 379j–72 shall be credited to this account (i.e., FDA's salaries and expenses appropriation account) and remain available until expended. Thus, the first legal condition was satisfied.
2	Description	The second condition requires a minimum spending from non-user fee appropriations on OTC monograph drug activities. The minimum spending amount is $12 million multiplied by an adjustment factor applicable to the fiscal year involved. The statute provides that FDA will be considered to have met this requirement in a fiscal year if the costs funded by such non-user fee appropriations and allocated for OTC monograph drug activities are not more than 15 percent below the level specified.
	Met By	The specified minimum spending level for FY 2023 is $13,300,812. In FY 2023, FDA obligated $42,520,319.80, exclusive of user fees, for the OMUFA program. As FDA spent more than the specified minimum amount in FY 2023, the second 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

OMUFA helps fund FDA's OTC monograph drug activities. Congress enacted authority for the OMUFA user fee program subsequent to negotiations between FDA and the OTC drug industry, in which FDA committed to achieve specified performance goals in terms of certain OTC monograph drug activities supported by fees. OMUFA provides additional resources to assist the Agency in conducting its important regulatory activities relating to OTC monograph drug products in a timely manner and ultimately helps provide the public with increased access to innovative OTC monograph drugs.

FDA will continue its efforts to meet and exceed its OMUFA program commitments, as agreed to by FDA and industry in the OMUFA Goals Document,[2] in the following areas:

- Hiring staff
- Developing and implementing an information technology (IT) platform
- Facilitating industry-initiated OMORs for innovations with associated timelines and performance goals
- Creating meeting management timelines, performance goals, and guidance documents
- Forecasting planned monograph activities
- Creating timelines and performance goals for specified safety changes to Drug Facts labeling
- Enhancing transparency with guidance documents regarding electronic submissions, submission content and format, dispute resolution, and consolidated proceedings
- Creating timelines and performance goals related to dispute resolution proceedings, resubmitted OMORs, and generally recognized as safe and effective finalization OMORs

G. Performance Summary

Beginning in March 2020, FDA experienced the unexpected onset of the COVID-19 public health emergency, the impact of which continued into FY 2023. During this emergency, the Agency appropriately shifted resources to prioritize its work focused on addressing the pandemic. Despite this, FDA managed to achieve a considerable number of the FY 2023 OMUFA performance objectives in support of FDA's OTC monograph drug activities.

Overall, by the end of FY 2023, OMUFA had met nine program enhancement commitments and missed one commitment (i.e., issuing a final guidance document on meetings). With the exception of the one missed commitment, all other commitments were completed on time. Details on the program performance can be found in the FY 2023 OMUFA Performance Report.

[2] See https://www.fda.gov/media/106407/download.

Financial Information

This section provides an overview of the program financials for OMUFA for FYs 2022 and 2023. 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 OMUFA financial position for FY 2022 and FY 2023. The financial notes included in the table can be found in **Appendix E.**

Table 1: OTC Monograph Drug User Fee Collections for FYs 2022 and 2023

Budgetary Resources	Notes	FY 2022	FY 2023
Target Revenue	Note 1	$23,888,000	$25,421,000
Total Carryover, Beginning of Year		$13,156,928	$20,978,557
Net Collections		$22,251,176	$26,964,369
Recoveries	Note 2	$0	$79,564
Total Budgetary Resources		**$35,408,104**	**$48,022,489**
Obligations	**Notes**	**FY 2022**	**FY 2023**
Total Payroll and Operating	Note 3	$12,816,307	$21,165,189
Total Rent	Note 4	$1,101,180	$1,048,168
Total Shared Services	Note 5	$512,060	$3,746,376
Total Obligations		**$14,429,547**	**$25,959,733**
Carryover	**Notes**	**FY 2022**	**FY 2023**
Total Carryover, End of Year		**$20,978,557**	**$22,062,757**

Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

Budgetary Resources: The "Total Budgetary Resources" component of **Table 1** illustrates the total user fee funding (i.e., the existing total carryover if applicable, and additional user fee collections). The "Target Revenue" is the annual revenue amount established for facility fees when fees for the fiscal year are set. The "Net Collections" are the amounts collected during the fiscal year, net of refunds that have taken place. A further explanation of these collections is provided in **Section I – User Fee Revenue**.

Section 744M of the FD&C Act specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation, additional dollar amounts, additional direct costs, and the operating reserve. FDA has applied those factors in the target revenue for annual fee setting, as shown on **Table 2**.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of OMUFA fee funds broken out into major expense categories. OMUFA fees may be expended only for costs to support "OTC monograph drug activities," as defined in section 744L (6) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix B**.

Carryover: OMUFA fees appropriated, collected, and not obligated at the end of the fiscal year remain available to support the OMUFA program in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or the "OMUFA carryover." Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting fees and the risk of a lapse in appropriations, so FDA can continue performing OTC monograph drug activities under such financial constraints. A further explanation of carryover is provided in **Section K – User Fee Carryover**.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for FY 2023. 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 facility fee-paying units differs from the number of fee-paying units estimated when fees are set each year.

Table 2: OTC Monograph Drug Facility Fee Revenue for FYs 2022 and 2023

Target Revenue	Notes	FY 2022	FY 2023
Base Amount		$8,000,000	$15,112,328
Inflation Adjustment	Note 6	$112,238	$308,805
Additional Dollar Amount	Note 10	$7,000,000	$6,000,000
Additional Direct Cost	Note 8	$7,000,000	$4,000,000
Operating Reserve Adjustment	Note 7	$1,776,083	$0
Target Revenue Total		**$23,888,000**	**$25,421,000**

Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

The process for setting the annual target revenue for facility fees is defined in the statute. The base amount for FY 2023 is defined in the statute as the total revenue for the prior fiscal year, not including any operating reserve or additional direct cost adjustments for that prior year, and then adjusted for the following factors, if applicable: inflation adjustment, additional dollar amount, additional direct costs, and operating reserve adjustment.

There is no annual target revenue for OMORs. OMOR fee rates for FY 2023 are from rates specified in the statute and adjusted for inflation.

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

Section 744M(a) of the FD&C Act specifies that fees are to be collected from qualifying owners of OTC monograph drug facilities and from submitters of qualifying OMORs. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. Net collections differ between the fiscal year and the cohort year. Cohort year collections reflect collections for a single year (e.g., FY 2023) across multiple fiscal years. Transactions such as late collections or refunds processed in a different fiscal year (e.g., a refund processed during FY 2023 for an FY 2022 payment) are displayed in **Tables 3a**, **3b**, and **3c**. Other data tables, though, use fiscal year data that solely show the activity within that single fiscal year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Fees collected and appropriated but not spent by the end of the fiscal year remain available for FDA to spend in future years because these fees are classified as no-year funding under FDA's annual appropriation (i.e., they are available until expended). The funds carried over from year to year are described in **Section K – User Fee Carryover**.

Tables 3a, **3b**, and **3c** outline the OMUFA collections by fee source and cohort year. Refer to **Section D** for more background and information on the OMUFA fee structure.

Table 3a: OMUFA Collections by Fee Source for Cohort Year 2022

Fees Collected	Target	Actual	% Diff
Facility Fees	$23,888,000	$24,395,166	2%
OMOR Tier 1 Fees	$0	$0	N/A
OMOR Tier 2 Fees	$0	$0	N/A
Total Collections	**$23,888,000**	**$24,395,166**	**2%**

Total Collections excludes over/duplicate payments and unapplied amounts.
Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

Table 3b: OMUFA Collections by Fee Source for Cohort Year 2023

Fees Collected	Target	Actual	% Diff
Facility Fees	$25,421,000	$23,811,012	(6)%
OMOR Tier 1 Fees	$0	$0	N/A
OMOR Tier 2 Fees	$0	$0	N/A
Total Collections	**$25,421,000**	**$23,811,012**	**(6)%**

Total Collections excludes over/duplicate payments and unapplied amounts.
Target Revenue has been rounded to the nearest thousand dollars.
All other numbers have been rounded to the nearest dollar.

Table 3c: OMUFA Collections by Fees Receivable for Cohort Years 2022 and 2023

Fees Receivable	Cohort Year 2022 Actuals	Cohort Year 2023 Actuals
Facility Fees	$11,130,545	$8,766,730
OMOR Tier 1 Fees	$0	$0
OMOR Tier 2 Fees	$0	$0
Total Receivables	**$11,130,545**	**$8,766,730**

Numbers have been rounded to the nearest dollar.

J. User Fee Obligations

OMUFA fees may be expended only for costs necessary to support "OTC monograph drug activities," as defined in section 744L(6) of the FD&C Act. For more information on the allowable and excluded costs, see **Appendix B.**

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

Table 4: OMUFA Obligations by Expense Category for FYs 2022 and 2023

User Fee Obligations	Notes	FY 2022	FY 2023
Payroll and Operating	Note 3		
CDER		$12,722,222	$20,623,979
ORA		$0	$0
HQ		$94,086	$541,210
Total Rent	Note 4	$1,101,180	$1,048,168
Total Shared Services	Note 5	$512,060	$3,746,376
Total Obligations		**$14,429,547**	**$25,959,733**

Numbers have been rounded to the nearest dollar.

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

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

- **Rent:** This amount 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 services organizations, such as human resources and IT, that provide support across the user fee programs.

Table 5 provides the total amount spent by FDA, as well as by each major FDA component that supports the OMUFA program for the past 3 fiscal years.

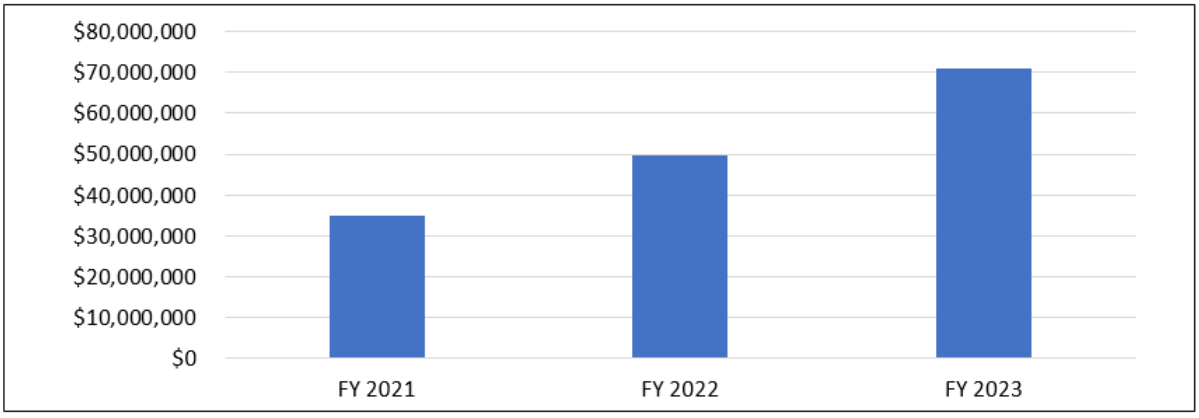
Table 5: OMUFA Program Total Costs by Organization as of September 30 of Each Fiscal Year

CATEGORY	FY 2021	FY 2022	FY 2023
CDER Spent($)	$24,880,226	$32,621,680	$41,045,293
CDER Percentage(%)	71%	66%	60%
ORA Spent($)	$7,602,736	$14,074,078	$23,129,339
ORA Percentage(%)	22%	28%	34%
HQ Spent($)	$2,547,697	$2,948,515	$4,305,420
HQ Percentage(%)	7%	6%	6%
Total Spent	**$35,030,659**	**$49,644,273**	**$68,480,052**

Numbers have been rounded to the nearest dollar, and percentages have been rounded to nearest whole.

Exhibit 4 provides an illustration of historical OMUFA costs.

Exhibit 4: Historical Total Costs by Fiscal Year



K. User Fee Carryover

OMUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the FDA's OTC monograph drug activities in future fiscal years.

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting fees and the risk of a lapse in appropriations. In order to mitigate those risks in FY 2023, the OMUFA program was authorized to make adjustment specified in section 744M(c)(2) of the FD&C Act. Additionally, in accordance with section 744M(a)(1)(D)(ii)(I) of the FD&C Act, facility fees are due on June 1 in FYs 2022 to 2025. Unlike most FDA user fee programs for which annual fees are aligned with the federal fiscal year and due on October 1 each year, the OMUFA program will always require carryover sufficient to cover payroll and operating expenses for the first 8 months of the following fiscal year (i.e., October 1 to May 31). Despite this collection timing challenge, the Agency has developed a robust 5-year spending plan that demonstrates that the OMUFA user fee revenues, which are essential to the success of the OTC monograph program, will be obligated in support of OTC monograph drug activities.

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

Table 6 provides the OMUFA carryover at the end of FY 2022 and FY 2023. The financial notes can be found in **Appendix E**.

Table 6: OMUFA Carryover for FYs 2022 and 2023

Carryover	Notes	FY 2022	FY 2023
Total Carryover, End of Year		**$20,978,557**	**$22,062,757**
OMUFA Continuity, Set Aside		($14,883,298)	($17,110,378)
Future Year Refunds Allowance, Set Aside	Note 9	($100,000)	($100,000)
Carryover Net of Set Aside, End of Year		**$5,995,259**	**$4,852,379**

Numbers have been rounded to the nearest dollar.

These terms are defined below:

- **Total Carryover, End of Year** – This is the total amount of unobligated fee funds at the end of the fiscal year.
- **OMUFA Continuity, Set Aside** – FDA will maintain a balance sufficient to sustain the Agency's OTC monograph drug activities for the first 8 months of the following fiscal year until the facility fees for the subsequent fiscal year are due and payable.
- **Future Year Refunds Allowance, Set Aside** – FDA maintains a small amount to provide for any refunds, as a matter of prudent operations. For

that purpose, a total of $100,000 in fee funds available for obligation is being set aside annually. See **Note 9** for additional details.

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

Table 7 reflects the amount of fees collected and the amount obligated during the current authorization period.

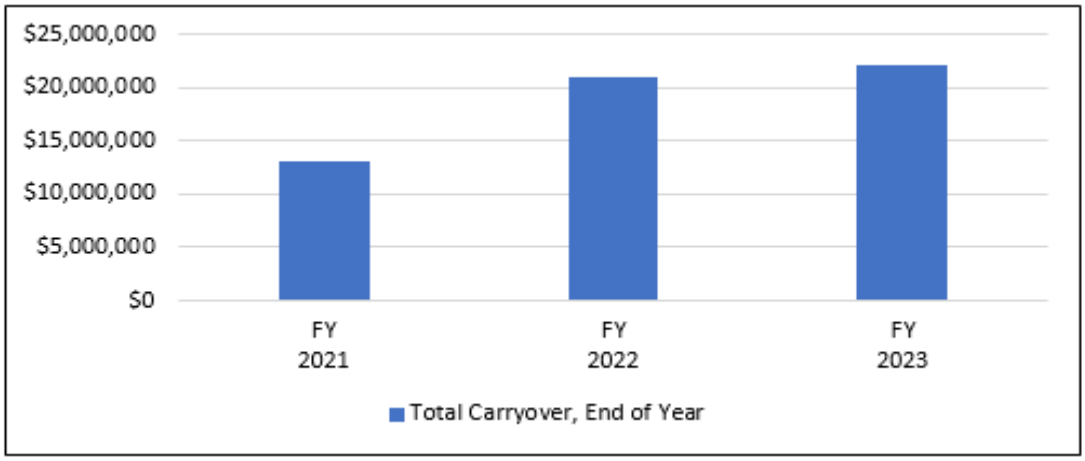
Table 7: OTC Monograph Drug User Fee Carryover by Reauthorization Period

	Notes	FY 2021	FY 2022	FY 2023
Total Carryover, Beginning of Year		$0	$13,156,928	$20,978,557
Net Collections		$20,103,265	$22,251,176	$26,964,369
Recoveries	Note 2	$0	$0	$79,564
Obligations		($6,946,337)	($14,429,547)	($25,959,733)
Total Carryover, End of Year		**$13,156,928**	**$20,978,557**	**$22,062,757**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective on the carryover for the last 3 fiscal years.

Exhibit 5: Historical Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees assessed and collected under section 744M of the FD&C Act, a certain amount of non-user-fee appropriations must be allocated for OTC monograph drug activities for that fiscal year. This is often referred to as a "non-user-fee spending trigger." The spending trigger was $12,474,816 for FY 2022 and $13,300,812 for FY 2023.

The non-user-fee spending trigger amount is determined by multiplying the base amount of non-user-fee appropriations allocated for human OTC monograph drug activities ($12 million) times the adjustment factor for each fiscal year following the base year of FY 2021. See **Note 8** for more details on the adjustment factor.

Table 8 provides the total amount spent on the OMUFA program for the past 3 fiscal years, as well as the dollar amount and percentages derived from user-fee and non-user-fee appropriations.

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

Funding Source	FY 2021	FY 2022	FY 2023
Non-User Fee Appropriations Obligated: Total ($)	$28,084,322	$35,214,725	$42,520,320
Non-User Fee Appropriations Obligated: Percent (%)	80%	71%	62%
User Fee Funds Obligated: Total ($)	$6,946,337	$14,429,547	$25,959,733
User Fee Funds Obligated: Percent (%)	20%	29%	38%
Total Obligated	**$35,030,659**	**$49,644,273**	**$68,480,052**

Numbers have been rounded to the nearest dollar and percentages have been rounded to nearest whole.

M. Full-Time Equivalents

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

As they relate to OMUFA, FTEs are referred to as "Process FTEs." Process FTEs are how FDA measures a paid staff year devoted to the OMUFA program. In Table 9, an FTE does not represent an accounting of individual people, but rather an FTE represents an estimate of labor hours expended on OTC monograph drug activities. Funding is distributed to FDA's Centers based on the workload to support payroll to accomplish the program goals.

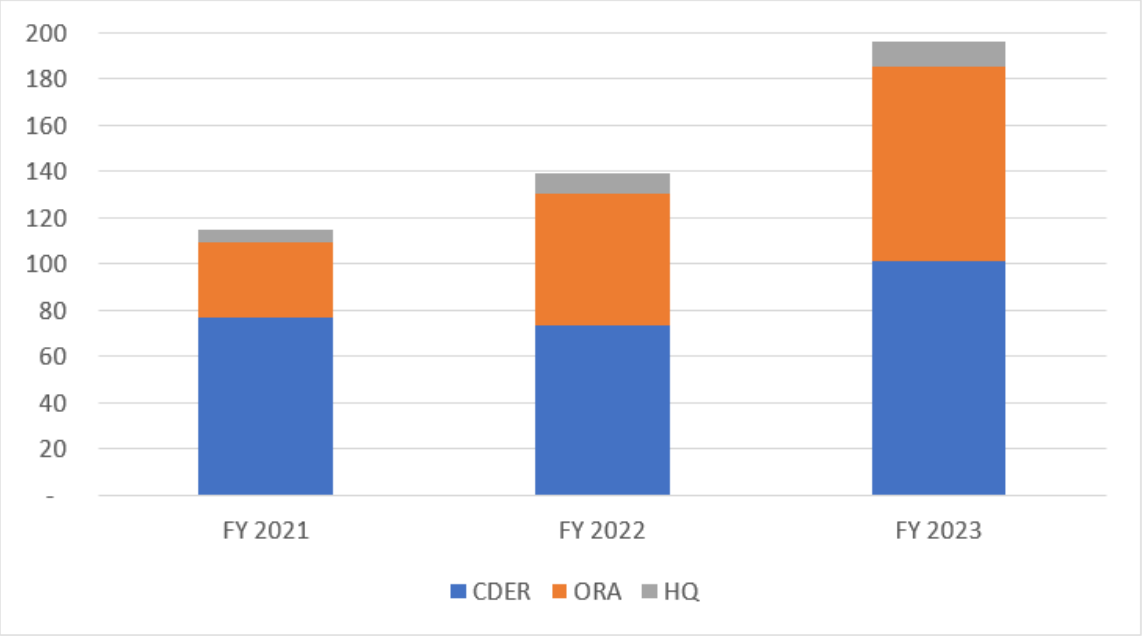
Table 9 presents total Process FTE levels, paid from user-fee and non-user-fee appropriations, that support the OMUFA program. The data cover the past 3 fiscal years and are arranged by FDA's organizational components (CDER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

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

Fiscal Year	FY 2021	FY 2022	FY 2023
CDER	77	74	101
ORA	32	57	84
HQ	6	9	11
TOTAL	**115**	**139**	**196**

Exhibit 6 provides the historical trend of FTE distribution across FDA's organizations for the past 2 fiscal years.

Exhibit 6: Total Process FTE Levels by FDA's Organizations



N. Internal Controls

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

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

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

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

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

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

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

1. Reporting controls to include business and IT controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk.

2. Charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs.

3. Controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and

4. Financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996.

In FY 2023, FDA's annual assessment of internal controls included tests of 94 business and IT controls across nine major transaction cycles and 21 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 11 IT controls related to the User Fee System. Further, in FY 2023, FDA enhanced its integration with HHS to focus on IT controls, alignment with HHS standardized IT controls guidance, and collaborate with HHS.

Annually, FDA conducts an improper payments risk assessment and performs improper payment testing to assess financial disbursements. In FY 2023, FDA completed the FDA FY 2023 Improper Payments risk assessment to identify FDA Programs that were susceptible to significant improper payments. Six FDA Programs—including Foods, Human Drugs, Biologics, CURES Activities, Reimbursable Program (Federal Sources), and Opioids – IMF Programs—were deemed to not be susceptible to significant improper payments. The Biologics Program and the Devices and Radiological Health Program were selected for improper payments transactional testing. Neither the Biologics nor the Devices and Radiological Health Programs were found to be susceptible to significant improper payments.

The Unified Financial Management System FDA-set-of-books—which is the Integrated Budget, and Acquisition Planning Systems (IBAPS)—and the User Fee System are compliant with HHS guidelines and with OMB Circular Appendix D, Management of Financial Management Systems - Risk and Compliance.

FDA has also implemented other internal control procedures, including the performance of Organizational Risk Reviews, which are reviews of targeted financial and non-financial management processes to identify potential recommendations to enhance internal controls. Also, FDA maintains a Continuous Monitoring Program to oversee

the timely implementation of corrective action plans for any deficiencies identified through any of its control assessments.

As a component of HHS, FDA's financial data is presented in HHS's consolidated financial statements. The FY 2023 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2023, 2022 and 2021, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2023 Assurance Statements found no material weaknesses or financial system nonconformances.

O. Risks and Challenges

Financial Risks and Mitigation

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

- **Under-Executing Planned Spend:** OMUFA budgetary resources have been underspent 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 will continue to enhance its planning and execution around the hiring of new staff and contract actions.

- **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 FDA's ability to spend the non-user-fee appropriations from the onset.

- **Lapse in Non-User-Fee Appropriations:** FDA is maintaining a certain level of operating reserves of carryover, which can be used to preserve program operations for a limited time in the event of a shutdown. For the OMUFA

program, FDA may maintain up to 10 weeks of operating reserves of carryover to help mitigate this risk.

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

- **Global Pandemic:** Although the public health emergency ended on May 11, 2023, there continues to be some degree of uncertainty regarding the potential long-term impact of COVID-19 on the collection of OMUFA facility user fees. FDA is continually monitoring these impacts and will seek to address financial ramifications as warranted.

In addition to these mitigation strategies, FDA implemented 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 the Agency's resources.

Strategic Challenges

FDA acknowledges that with any new user fee program, such as with the OMUFA program, challenges will arise. A major challenge that persisted for the OMUFA program into FY 2023 was that many companies in the OTC industry continued adjusting to the statutorily changed regulatory landscape in terms of OTC monograph reform (as enacted under the CARES Act). Companies also are still adjusting to the OMUFA fee obligations associated with the manufacturing or processing of OTC monograph drug products and submission of OMORs.

Appendices

A. Reporting Requirements

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

Requirement	Details
Section 744N(b) of the FD&C Act	The law requires that a fiscal report, beginning with FY 2021, 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.
Section 744N(d) of the FD&C Act	The law requires that in developing recommendations for the reauthorization of OMUFA for fiscal years after FY 2025, FDA must provide the proposed recommendations to specified congressional committees and publish the recommendations in the *Federal Register.*

B. Allowable and Excluded Costs for OMUFA

Section 744L(6) of the FD&C Act defines the term "OTC monograph drug activities," in general, as the activities associated with OTC monograph drugs and inspection of facilities associated with such products. In summary, costs related to the following have been attributed to OTC monograph drug activities:

Included Activities
1. The activities necessary for review and evaluation of OTC monographs and OMORs, including: a. Orders proposing or finalizing applicable conditions of use for OTC monograph drugs; b. Orders affecting status regarding general recognition of safety and effectiveness of an OTC monograph ingredient or combination of ingredients under specified conditions of use; c. All OTC monograph drug development and review activities, including intra-agency collaboration; d. Regulation and policy development activities related to OTC monograph drugs; e. Development of product standards for products subject to review and evaluation; f. Meetings referred to in section 505G(i) of the FD&C Act; g. Review of labeling prior to issuance of orders related to OTC monograph drugs or conditions of use; and h. Regulatory science activities related to OTC monograph drugs. 2. Inspections related to OTC monograph drugs. 3. Monitoring of clinical and other research conducted in connection with OTC monograph drugs. 4. Safety activities with respect to OTC monograph drugs, including: a. Collecting, developing, and reviewing safety information on OTC monograph drugs, including adverse event reports; b. Developing and using improved adverse event data-collection systems, including information technology systems; and c. Developing and using improved analytical tools to assess potential safety risks, including access to external databases. 5. Other activities necessary for implementation of section 505G of the FD&C Act.

Section 744L(3) of the FD&C Act defines the term “costs of resources allocated for OTC monograph drug activities” as expenses in connection with OTC monograph drug activities for:

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 744M of the FD&C Act and accounting for resources allocated for the review of order requests and inspections related to monograph drugs.

The OMUFA program excludes costs related to the following:

Excluded Activities
1. Activities necessary for the review of new drug applications, biologic license applications, and abbreviated new drug applications. 2. The issuance of correspondence unrelated to OTC monograph drugs. 3. Inspections unrelated to OTC monograph drugs. 4. Monitoring of clinical and other research unrelated to OTC monograph drugs. 5. Post market safety activities unrelated to OTC monograph drugs. 6. Other activities that are not necessary for implementation of section 505G of the FD&C Act.

C. User Fee Program History

Section 744M of the FD&C Act authorizes FDA to assess and collect user fees from the OTC monograph drug industry to supplement the non-user-fee appropriations that the Agency spends on OTC monograph drug activities. FDA spends fee revenues and non-user-fee appropriations to hire, support, and maintain personnel for OTC monograph drug activities to ensure the American public has access to safe, high-quality, and innovative OTC monograph drugs.

D. Conditions for Assessment and Use of Fees

Introduction

Section 744M of the FD&C Act specifies two legal conditions that must be met each fiscal year for FDA to collect and spend OTC monograph drug user fees. This appendix describes these conditions.

Legal Conditions

Exhibit 7 provides the details regarding each legal condition contained in the applicable sections of the FD&C Act.

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	744M(f)(1)	Fees shall be collected and available for obligation only to the extent and in the amount provided in advance in appropriations Acts.
2	744M(f)(2)(B)	Fees shall be available to defray increases in the costs of the resources allocated for OTC monograph drug activities (including increases in such costs for an additional number of full-time equivalent positions to be engaged in such activities), only if FDA allocates for such purpose an amount for such fiscal year (excluding amounts from fees) no less than $12,000,000, multiplied by the adjustment factor applicable to the fiscal year involved under section 744M(c)(1) of the FD&C Act.

Adjustment Factor Used in Meeting the Second Legal Condition (Spending Trigger)

To determine the amount of the non-user fee "spending trigger" under section 744M(f)(2)(B) of the FD&C Act (as mentioned in the report's **Section L – Non-User Fee Appropriations**), FDA must calculate and incorporate an adjustment factor "applicable to the fiscal year involved" under section 744M(c)(1) of the FD&C Act. Under the statute, there is no defined "adjustment factor" for OMUFA purposes; however, given the statutory reference to "the adjustment factor applicable to the fiscal year involved under subsection (c)(1)" (i.e., section 744M(c)(1)), the Agency utilizes the inflation adjustment percentage described in section 744M(c)(1)(C) of the FD&C Act. That provision states that for each of fiscal years 2022 and 2023, the inflation adjustment percentage is equal to the average annual percent change that occurred in the Consumer Price Index (CPI) for urban consumers (Washington-Baltimore, DC-MD-

VA-WV; Not Seasonally Adjusted; All items; annual index) for the first 3 years of the preceding 4 years of available data (section 744M(c)(1)(C)(i) of the FD&C Act).

As a result of a geographical revision made by the Bureau of Labor Statistics in January 2018, the "Washington, DC-Baltimore" index was discontinued and replaced with two separate indices (i.e., the "Washington-Arlington-Alexandria" and "Baltimore-Columbia-Towson" indices). To apply a CPI that best reflects the geographic region in which FDA is located and that provides the most current data available, the "Washington-Arlington-Alexandria" index will be used in calculating the adjustment factor for FY 2022 and subsequent years.

For FY 2023, the spending trigger amount is $13,300,812.

E. Financial Notes

Note 1. Annual Target Revenue Methodology

The estimated user fee collections are based on the facility fee target revenue (i.e., base revenue adjusted for inflation, additional direct costs, additional dollar amounts, and the operating reserve).

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. Payroll And Operating Costs

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support OTC monograph drug activities. If an operating activity solely supports OTC monograph drug activities, it will be fully funded by the program. If the operating activity is shared, OMUFA 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 OTC monograph drug activities, a portion of those charges is paid from non-user-fee

appropriations and a portion is paid from OMUFA 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 the rental of space and all recurring services for building operations such as overtime, utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent-related costs each Center pays is directly related to the square footage occupied by that Center.

Note 5. Shared Service Costs

FDA has several shared service organizations, located with the Working Capital Fund (WCF), that provide support across the user fee programs.[3] The shared service organizations in FY 2023 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.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA's employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Digital Transformation**: 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. Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Division of Budget Execution and Control:** Initiates, monitors and analyzes FDA's budget resources. The Agency's budget is comprised of several appropriation accounts including Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.

[3] FDA has a Cost Allocation and Recovery Framework to improve its financial management of user fee resources. Congress authorized FDA to establish a WCF to finance centralized services (see section 722 of Division A of Public Law 115-141).

- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.
- **Office of Human Capital Management:** Provides human resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust and mutual respect.
- **Office of Talent Solutions:** Provides high quality and efficient human resource solutions that enable FDA to hire a talented and qualified workforce.
- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA's leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

Note 6. Inflation Adjustment

The inflation adjustment adjusts the base revenue 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 2023 was 2.0434 percent.

Note 7. Operating Reserve Adjustment

Maintaining an appropriate level of operating reserves of carryover enables FDA to mitigate financial risks to the program so FDA can continue performing OTC monograph drug activities under financial constraints. For example, an appropriate level of operating reserves of carryover mitigates the risk of under-collecting fees or the risk of a lapse in appropriations. Under OMUFA, FDA may further increase the FY 2023 facility fee revenue and fees if such an adjustment is necessary to provide up to 10 weeks of operating reserves of carryover user fees for OTC monograph drug activities (see section 744M(c)(2)(A) of the FD&C Act). However, under the statute, if the carryover exceeds 10 weeks of operating reserves, FDA is required to decrease fees to provide for not more than 10 weeks of such operating reserves of carryover user fees (see section 744M(c)(2)(C) of the FD&C Act).

FDA did not apply an operating reserve adjustment for FY 2023.

Note 8. Additional Direct Cost Adjustment

Under OMUFA, $7 million is added to the facility fee revenues for FY 2023 to account for additional direct costs (see section 744M(c)(3)(A) of the FD&C Act).

Note 9. Future Year Refunds Allowance, Set Aside

As stated in section 744M(a)(2)(D) of the FD&C Act,

> If the Secretary determines that an OTC monograph request initially characterized as Tier 1 shall be recharacterized as a Tier 2 OTC monograph order request, and the requestor has paid a Tier 1 fee . . . the Secretary shall refund the requestor the difference between the Tier 1 and Tier 2 fees.

As stated in section 744M(a)(2)(E) of the FD&C Act, “The Secretary shall refund 75 percent of the fee paid . . . for any order request which is refused for filing or was withdrawn before being accepted or refused for filing.”

As stated in section 744M(a)(2)(F) of the FD&C Act, an OMOR “that was submitted but was refused for filing or was withdrawn before being accepted or refused for filing, shall be subject to the full fee . . . upon being resubmitted or filed over protest.”

As stated in section 744M(a)(2)(G) of the FD&C Act,

> If an order request is withdrawn after the order request was filed, the Secretary may refund the fee or a portion of the fee if no substantial work was performed on the order request after the application was filed. The Secretary shall have the sole discretion to refund a fee or a portion of the fee . . . . A determination by the Secretary concerning a refund under this subparagraph shall not be reviewable.

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

Note 10. Additional Dollar Amounts

Section 744M(b)(2)(E) of the FD&C Act specifies that certain additional dollar amounts are included in the total target revenue to be generated by facility fees for each fiscal year. For FY 2023, the additional dollar Amount was $6 million.

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