Financial Report to Congress

Over-the-Counter Monograph Drug User Fee Program

FY 2024

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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 fourth OMUFA financial report and covers fiscal year (FY) 2024.

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 2024, 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 2024, FDA had net collections of $32 million in OTC monograph drug user fees, spent $30 million in user fees for OTC monograph drug activities, and carried $24 million forward for future fiscal years (of which $22 million was continuity set aside).

OMUFA user fees and non-user-fee appropriations in FY 2024 supported 197 full-time equivalents, including salaries and operational expenses, to support OTC monograph drug activities. Detailed program accomplishments can be found in the OMUFA performance report.[1]

[1] OMUFA performance reports are available at https://www.fda.gov/about-fda/user-fee-performance-reports/omufa-performance-reports.

Report Overview

A. Scope

This financial report addresses the implementation and use of fees for the over-the-counter (OTC) monograph drug user fee program (referred to as "OMUFA") by the Food and Drug Administration (FDA or Agency) during the period of October 1, 2023, through September 30, 2024. It 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 2024 user fee program financials, revenue, obligations, carryover, total costs of OTC monograph drug activities covered by OMUFA fees and non-user-fee appropriations, and full-time equivalents (FTEs).

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 (which concludes September 30).

C. 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 1 outlines the OMUFA user fee structure.

Exhibit 1: 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*.[2]

OMUFA user fees collected are not a fee for service. User fees 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.

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.

[2] Additional information is available at https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa.

Exhibit 2 describes those legal conditions and provides a brief explanation as to how those legal conditions were met.

Exhibit 2: 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, 2024 (Division B of the Consolidated Appropriations Act, 2024 (Public Law 118-42, which the President signed on March 9, 2024)), 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 2024 is $12,899,561. In FY 2024, FDA obligated $38,422,948 exclusive of user fees, for the OMUFA program. As FDA spent more than the specified minimum amount in FY 2024, 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 B**.

Financial Information

This section provides an overview of the program financials for OMUFA for FY 2023 and FY 2024. These financials include user fee revenue, obligations, carryover, non-user-fee appropriations, and FTEs.

D. User Fee Program Financials

Table 1 represents a summary of the OMUFA financial position for FY 2023 and FY 2024.

Table 1: OMUFA Program Financials for FYs 2023 and 2024

Budgetary Resources	FY 2023	FY 2024
Total Carryover, Beginning of Year	$20,978,557	$22,062,757
Net Collections	$26,964,369	$31,789,414
Recoveries	$79,564	$206,482
Total Budgetary Resources	**$48,022,489**	**$54,058,652**
Obligations	**FY 2023**	**FY 2024**
Total Payroll	$10,214,120	$14,955,901
Total Operating	$10,951,069	$10,757,090
Total Rent	$1,048,168	$1,058,650
Total Shared Services	$3,746,376	$3,238,793
Total Obligations	**$25,959,733**	**$30,010,434**
Carryover	**FY 2023**	**FY 2024**
Total Carryover, End of Year	**$22,062,757**	**$24,048,218**

Budgetary Resources: Total Budgetary Resources is the total user fee funding (i.e., the existing total carryover, user fee collections, and recoveries). Net Collections are the amounts collected during the fiscal year, net of refunds that have taken place. Recoveries account for funds de-obligated from prior year obligations. For example, recoveries could include funding from a contract that ended in a prior year and was not expended. See **Section E** for more on user fee revenue**.**

Obligations: Total Obligations is 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 A.**

Carryover: OMUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support OTC monograph drug activities in future fiscal

years. In this report, such fee funds, are referred to as the "total carryover" or "OMUFA carryover." See **Section G** for more on carryover.

E. User Fee Revenue

The OMUFA facility fees are set each year based on the target revenue amount. The process for setting the annual target revenue is defined in the statute and described below. By statute, OMOR fees are not included in target revenue.[3] **Table 2** outlines the annual target revenue amounts for FY 2023 and FY 2024.

Table 2: OMUFA Facility Fee Revenue for FYs 2023 and 2024

Target Revenue	FY 2023	FY 2024
Annual Base Revenue Amount	$15,112,328	$21,421,133
Inflation Adjustment	$308,805	$832,232
Additional Dollar Amount	$6,000,000	$7,000,000
Operating Reserve Adjustment	$0	$0
Additional Direct Cost	$4,000,000	$3,000,000
Target Revenue Total*	**$25,421,000**	**$32,253,000**

*Target Revenue Total is rounded to the nearest thousand dollars.

Annual Base Revenue Amount: The base amount for FY 2024 was the target revenue from FY 2023 not including any operating reserve or additional direct cost adjustment.

Inflation Adjustment: The inflation adjustment maintains the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that adjusts 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 utilized in FY 2024 was 3.8851 percent.

Additional Dollar Amount: OMUFA provides for funding used in the hiring of 105 new positions to support the workload associated with OTC monograph drug activities, as contemplated by the OMUFA I negotiations between FDA and industry. These 105 new positions are scheduled to be hired over the 5 fiscal years of OMUFA I (i.e., FY 2021 to FY 2025).[4] 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.

Operating Reserve Adjustment: The operating reserve adjustment helps FDA manage financial risks potentially affecting its OTC monograph drug activities while ensuring the

[3] See section 744M(b) of the FD&C Act, which bases target revenue on facility fees.
[4] The FY 2023 OMUFA Performance Report is available at https://www.fda.gov/media/176430/download?attachment.

program maintains an appropriate amount of operating reserves of carryover balances for such activities. For FY 2024, section 744M(c)(2) of the FD&C Act authorizes FDA to increase the fee revenue and fees to provide for up to 10 weeks of operating reserves of carryover balances for OTC monograph drug activities. If the operating reserve is expected to exceed 10 weeks of OTC monograph drug activities, this adjustment requires lowering the annual revenue amount to provide for not more than 10 weeks of such operating reserves. (See **Appendix C.2** for additional details).

No operating reserve adjustment was applied for FY 2024.

Additional Direct Cost Adjustment: The additional direct cost adjustment under section 744M(c)(3) of the FD&C Act helps support non-payroll expenses associated with OTC monograph drug activities. The amount of the adjustments for each year are specified in the statute.

Target Revenue Total: This is the summation of the base revenue and the adjustments described above, rounded to the nearest thousand dollars. This amount is the amount that is intended to be collected in facility fees for the respective fiscal year and serves as the basis for setting the facility fee amounts.

FDA does not automatically receive the target revenue amount. Fees are collected throughout the fiscal year and the actual amount of fee dollars collected will vary from the target revenue based on the number of facility fees paid in any given 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.

Net Collections: Although the amount of actual collections varies, FDA generally assumes, for planning purposes, that net collections from facility fees will equal the target revenue amount. Net collections represent the total collections minus any refunds that occurred during the fiscal year, regardless of the year the fee was due. The net collections are reported in **Table 1** above.

Cohort Year Collections: User fee collections are generally recognized and reported in the fiscal year that the fee was originally due (referred to as the "cohort year").[5] Totals reported are after any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates prior years' numbers reported in the current report to account for any collections or refunds processed after publication of the prior year reports.

[5] For example, a fee originally due in FY 2023 but received in FY 2024 is attributed in FY 2023 cohort year collections.

In FY 2024, cohort year collections of facility fees fell short of the target revenue. See **Section G** below.

Tables 3a and **3b** outline the OMUFA collections by fee source and cohort year. **Table 3c** shows the outstanding amounts that are still owed for Cohort Years 2023 and 2024. Once any of these amounts are collected, they will be recognized as revenue in the corresponding cohort year. Refer to **Section C** for more background and information.

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

Fees Collected	Estimated†	Actual	% Diff
Facility Fees	$25,421,000	$25,390,617	0%
OMOR Tier 1 Fees	N/A	N/A	N/A
OMOR Tier 2 Fees	N/A	N/A	N/A
Total Collections	**$25,421,000**	**$25,390,617**	**0%**

† Estimated values were taken from the OMUFA User Fee Rates for FY 2023.
Percentage differences are rounded to the nearest whole percentage.

Table 3b: OMUFA Collections by Fee Source for Cohort Year 2024

Fees Collected	Estimated†	Actual	% Diff
Facility Fees	$32,253,000	$29,040,566	(10%)
OMOR Tier 1 Fees	N/A	$537,471	N/A
OMOR Tier 2 Fees	N/A	N/A	N/A
Total Collections	**$32,253,000**	**$29,578,037**	**(10%)**

† Estimated values were taken from the OMUFA User Fee Rates for FY 2024.
Percentage differences are rounded to the nearest whole percentage.

Table 3c: OMUFA User Fee Receivable by Fee Source for Cohort Years 2023 and 2024

Fees Receivable	Cohort Year 2023 Actuals	Cohort Year 2024 Actuals
Facility Fees	$7,884,535	$11,855,959
OMOR Tier 1 Fees	N/A	N/A
OMOR Tier 2 Fees	N/A	N/A
Total Receivables	**$7,884,535**	**$11,855,959**

F. 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 A**.

Table 4 provides a comparison of user fee obligations by expense category during the past 2 fiscal years.

Table 4: OMUFA Obligations by Expense Category for FYs 2023 and 2024

User Fee Obligations	FY 2023	FY 2024
Payroll	**$10,214,120**	**$14,955,901**
CDER	$9,900,247	$14,211,303
ORA	$0	$0
HQ	$313,873	$744,598
Operating	**$10,951,069**	**$10,757,090**
CDER	$10,723,732	$10,559,035
ORA	$0	$0
HQ	$227,336	$198,055
Total Rent	$1,048,168	$1,058,650
Total Shared Services	$3,746,376	$3,238,793
Total Obligations	**$25,959,733**	**$30,010,434**

Payroll and Operating Costs: These obligations provide for certain payroll and operating costs for which OMUFA fees may be expended to support OTC monograph drug activities, as defined 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. See **Appendix A** for a listing of those activities. The payroll and operating costs associated with the OMUFA program are based on obligations attributed to CDER, ORA, and HQ.

Center employees are required to report their time in an activity-based reporting system. This allows FDA to ensure that user fee funds are only supporting payroll proportional to the time invested in allowable activities.

For operating activities (e.g., certain contracting services), OMUFA fee 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 can be fully funded by OMUFA fees (and/or non-user fee appropriations). If the operating activity is supported by multiple user fee programs, OMUFA fees may fund the activity up to the appropriate proportion of the benefit from such activity that accrues to OTC monograph drug activities.

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 allowable 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. The amount of rent and rent-related costs each Center pays is directly related to the square footage occupied by that Center.

Shared Services: FDA has several shared service programs, located within the Working Capital Fund (WCF), that provide support for activities across the Agency, such as human resources and information technology (IT). **Appendix C.1** provides a full list of the offices that constitute the WCF.

Table 5 provides the total amount obligated by each FDA organization on the OTC monograph drug activities for the past 4 fiscal years, including both user fee and non-user-fee appropriations. As illustrated by the table, costs in FY 2024 were steady relative to 2023. The percentage spent by each FDA organizational component has fluctuated slightly based on public health priorities and the program's initial growth patterns.

Table 5: OMUFA Program Historical Trend of Total Costs by Organization as of September 30 for FYs 2021 to 2024

Total Cost by Organization	FY 2021	FY 2022	FY 2023	FY 2024
CDER Spent($)	$24,880,226	$32,621,680	$41,045,293	$43,976,331
CDER Percentage(%)	71%	66%	60%	65%
ORA Spent($)	$7,602,736	$14,074,078	$23,129,339	$20,048,150
ORA Percentage(%)	22%	28%	34%	29%
HQ Spent($)	$2,547,697	$2,948,515	$4,305,420	$4,151,759
HQ Percentage(%)	7%	6%	6%	6%
Total Spent	**$35,030,659**	**$49,644,273**	**$68,480,052**	**$68,176,240**

G. 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. This balance is referred to as the "total carryover" or "OMUFA carryover."

The net change in OMUFA carryover each year is equal to net collections minus net obligations. This is demonstrated best in **Table 6** below.

Table 6: OMUFA User Fee Carryover for the Current Reauthorization Period

Current Carryover	FY 2021	FY 2022	FY 2023	FY 2024
Total Carryover, Beginning of Year	$0	$13,156,928	$20,978,557	$22,062,757
Net Collections	$20,103,265	$22,251,176	$26,964,369	$31,789,414
Recoveries	$0	$0	$79,564	$206,482
Obligations	($6,946,337)	($14,429,547)	($25,959,733)	($30,010,434)
Total Carryover, End of Year	**$13,156,928**	**$20,978,557**	**$22,062,757**	**$24,048,219**

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 financial challenges associated with a potential lapse in appropriations, so that the FDA can continue performing activities related to OTC monograph drug activities under such

financial constraints, to the extent available carryover remains available. FDA may also set aside available user fee funds in the carryover for certain purposes, including, for example, for processing future year refunds.

As noted in **Section E** above, under OMUFA, FDA may further increase the FY 2024 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. However, under the statute, if the carryover exceeds 10 weeks of operating reserves, FDA is required to decrease fee revenue and fees to provide for not more than 10 weeks of such operating reserves of carryover user fees. FDA did not apply an operating reserve adjustment for FY 2024. **Appendix C.2** provides more details on how the need for any operating reserve adjustment is assessed.

Table 7 demonstrates the status of the OMUFA carryover at the end of FY 2023 and FY 2024.

Table 7: OMUFA Carryover for FYs 2023 and 2024

Carryover	FY 2023	FY 2024
Total Carryover, End of Year	**$22,062,757**	**$24,048,219**
OMUFA Continuity, Set Aside	($17,110,378)	($21,708,995)
Future Year Refunds Allowance, Set Aside	($100,000)	($88,000)
Carryover Net of Set Aside, End of Year	**$4,852,379**	**$2,251,224**

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. FDA estimated future year refunds set aside using a 3-year average of actual refunds from the most recently complete prior fiscal years. The estimated amount of $88,000 in fee funds available for obligation is being set aside. See **Appendix C.3** for additional details.

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

The operations in FY 2024 resulted in a net increase of the carryover of $1,985,462, from $22,062,757 at the end of FY 2023 to $24,048,219 at the end of FY 2024. Although FY 2024 cohort fee collections were 10 percent lower than estimated, they were offset by continued collections from the FY 2023 cohort (see **Tables 3a** and **3b**). Obligations for the year (see **Table 4**) were also lower than the estimated target revenue by approximately seven percent (see **Table 2**).

H. 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 $12,899,561 for FY 2024, less than the $38,165,806 for non-user fee appropriations obligated for FY 2024, meaning the trigger was met.

The non-user fee spending trigger amount is determined by multiplying a base amount of non-user fee appropriations ($12 million)[6] times the adjustment factor for the applicable fiscal year. See **Appendix B.1** for more details on the adjustment factor.

Table 8 provides the total amount spent on the OMUFA supported OTC monograph drug activities for the past 4 fiscal years, as well as the dollar amount and percentages derived from user fee and non-user fee appropriations.

Table 8: Historical OTC Monograph Drug Activities Obligations by Funding Source as of September 30 of Each Fiscal Year

Obligations by Funding Source	FY 2021	FY 2022	FY 2023	FY 2024
Non-User-Fee Appropriations Obligated: Total ($)	$28,084,322	$35,214,725	$42,520,320	$38,165,806
Non-User-Fee Appropriations Obligated: Percent (%)	80%	71%	62%	56%
User Fee Funds Obligated: Total ($)	$6,946,337	$14,429,547	$25,959,733	$30,010,434
User Fee Funds Obligated: Percent (%)	20%	29%	38%	44%
Total Obligated	**$35,030,659**	**$49,644,273**	**$68,480,052**	**$68,176,240**

I. 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 it specifically relates to OMUFA, FTEs are referred to as "Process FTEs." Process FTEs are how FDA measures a paid staff year devoted to OTC monograph drug activities. 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

[6] See section 744M(f)(2)(B) of the FD&C Act.

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 OTC monograph drug activities. 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 programs (facilities, procurement, IT services, etc.) are included in the FTE levels for various components.

Table 9: Historical Trend of Total Process FTEs Utilized by Organization as of September 30 for FYs 2021 to 2024

Total Process FTEs	FY 2021	FY 2022	FY 2023	FY 2024
CDER	77	74	101	115
ORA	32	57	84	72
HQ	6	9	11	10
TOTAL	**115**	**139**	**196**	**197**

Management Assurance

FDA maintains a strong internal control culture in order to support data-driven decision making, reliable financial forecasting, and accountability for resource use and to ensure compliance with laws, including:

- Federal Managers' Financial Integrity Act (FMFIA) – This act requires agencies to establish internal controls that provide a reasonable assurance of effective and efficient operations, compliance with applicable laws, and reliable financial reporting. This act requires agencies to comply with federal financial management systems requirements, ensuring that transactions are properly recorded, and financial reports are reliable.

- OMB Circular A-123 – This sets the standards for internal controls and requires agencies to implement internal control assessments, including the management of risks and ensuring accountability.

- Government Accountability Office Standards for Internal Control (Green Book) – This provides the framework for designing, implementing, and operating an effective internal control system within the federal government.

- Improper Payments Elimination and Recovery Act – This requires agencies to identify and reduce improper payments and recover overpayments when they occur.

- Federal Information Security Modernization Act – This addresses internal controls related to information security, ensuring the protection of federal information systems.

Additionally, FDA established three councils to govern oversight and accountability:

- Office of Finance, Budget, Acquisitions, and Planning (OFBAP) Strategic Council: The OFBAP Strategic Council strengthens FDA's financial management processes, enhancing integrity, accountability, and compliance with federal regulations. Membership: Chief Financial Officer (CFO) serves as the Executive Sponsor and the Deputy Chief Financial Officer chairs the council, with OFBAP Directors and representatives from each FDA Center and Office.

- Enterprise Risk Management Council: The council oversees FDA's Enterprise Risk Management Program, managing the Agency's Enterprise Risk Profile and ensuring alignment with FMFIA, OMB Circular A-123, OMB Circular A-11, the Green Book, and Department of Health and Human Services guidelines. Membership: The council is chaired by the Chief Operating Officer, with a Center Director as Co-Chair and the CFO as President Pro Tempore. Senior executive representatives from each FDA Center and Office serve as members.

- User Fee Financial Management Committee: The committee oversees and ensures FDA's compliance with sound financial management practices and statutory provisions governing user fees, providing oversight for resource needs, financial planning, and forecasting. The CFO serves as the committee Chairman, a Program Representative serves as the Program Vice Chairman,

and voting members include the Executive Officers from each FDA Center and Office.

Appendices

A. Allowable and Excluded Costs and Activities 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:

Exhibit 3: Included 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:

Exhibit 4: Included Expenses

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 products and activities:

Exhibit 5: Excluded Products and Activities

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.

B. Conditions for Assessment and Use of Fees

B.1. Adjustment Factor

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 H– 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 a calculation with the inflation adjustment percentage described in section 744M(c)(1)(C) of the FD&C Act. That provision states that for each of FYs 2024 and 2025, the inflation adjustment percentage is the sum of the average annual percent change in the cost, per FTE position of the FDA, of all personnel compensation and benefits paid with respect to such positions for the first 3 years of the preceding 4 fiscal years, multiplied by the proportion of personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years; and the average annual percent change that occurred in the Consumer Price Index for urban consumers (Washington-Baltimore, DC–MD–VA–WV; Not Seasonally Adjusted; All items; Annual Index)[7] for the first 3 years of the preceding 4 years of available data multiplied by the proportion of all costs other than personnel compensation and benefits costs to total costs of OTC monograph drug activities for the first 3 years of the preceding 4 fiscal years (section 744M(c)(1)(C)(ii) of the FD&C Act).

For FY 2024, the spending trigger amount is $12,899,561.[8]

B.2. Legal Conditions

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.

Exhibit 6 provides the details regarding each legal condition contained in the applicable sections of the FD&C Act.

[7] 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 has been used in calculating the inflation adjustment percentage.

[8] The spending trigger thresholds reported in the OMUFA financial reports for FYs 2022 and 2023 were slightly higher than should have been reported, due to a minor discrepancy in applicable calculations. However, this discrepancy in no way affected the Agency's meeting the OMUFA "spending trigger" legal condition for those prior fiscal years, because for each of those fiscal years, FDA obligated amounts for OTC monograph drug activities, exclusive of user fees, well in excess of the specified minimum amount.

Exhibit 6: 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.

C. Supplemental Financial Information

C.1. Shared Service Costs

FDA has several shared service organizations, located within the WCF, that provide support across the user fee programs. The shared service organizations in FY 2024 include:

- **Office of Digital Transformation:** Provides the vision and leadership in IT, data, and cybersecurity needed to advance FDA's mission and strategic priorities.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **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 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 Facilities, Engineering, and Mission Support Services:** Provides FDA employees with office and laboratory facilities.
- **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 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 Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.

- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting public health by enhancing the safety and security of all personnel, facilities, and information.

- **Office of Talent Solutions:** Provides high quality and efficient solutions that enable FDA to hire a talented and qualified workforce.

C.2. Operating Reserve Adjustment

For FY 2024, the OMUFA program was authorized to make an operating reserve adjustment as 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 generally due on the first business day of June in FYs 2022 to 2025. Unlike most FDA drug user fee programs for which receipt of annual fees is aligned with the start of the federal fiscal year, with fees due on October 1 each year, the OMUFA program requires 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.

Under OMUFA, FDA may further increase the FY 2024 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).

C.3. 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 re-characterized 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.

Table 10 outlines the actual refunds by fiscal year that are used to calculate the estimated refund set aside.

Table 10: OMUFA User Fees Estimated Future Year Refunds Allowance, Set Aside

Estimated Refunds Set Aside	FY 2021	FY 2022	FY 2023	3-Year Average
Actual Refunds	$0	($38,823)	($225,953)	($88,000)

3-Year Average is rounded to the nearest thousand dollars.

The FY 2024 actual refunds for OMUFA were $273,04.

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