FY 2021

FINANCIAL REPORT
TO CONGRESS

for the

OVER-THE-COUNTER MONOGRAPH DRUG USER FEE PROGRAM

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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 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). FDA refers to the OTC Monograph Drug User Fee Program as "OMUFA" throughout this document. Section 744N(b) of the FD&C Act requires the Food and Drug Administration (FDA or Agency) to report annually on the financial aspects of OMUFA implementation.

The first OMUFA financial report covers fiscal year (FY) 2021. However, because FY 2021 is the first year of this user fee program, this report covers only the period from March 26, 2021 (the publication date of the FY 2021 OMUFA fee notice) to the end of FY 2021 (i.e., September 30, 2021).

A challenge faced with OMUFA in its first year was that the setting of fees did not occur until midway through the year, in March 2021. As a result, only half of the fiscal year was available to assess and collect fees, and the amount of time to obligate user fees before the end of FY 2021 was shortened. More significantly, the due date for annual facility fees, which constitute the bulk of OMUFA revenues, does not occur until late in the fiscal year (e.g., during the third fiscal quarter on June 1). As a result, the Agency must rely on carryover to sustain its OTC monograph drug activities until the subsequent fiscal year's facility fees are due and payable.

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 $12,000,000 of appropriations (excluding user fees) multiplied by an adjustment factor.

FDA met the two legal conditions in FY 2021, 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 2021, FDA had net collections of $20 million in OTC monograph drug user fees, spent $7 million in user fees for OTC monograph drug activities, and carried $13 million forward for future fiscal years.

OMUFA user fees and non-user-fee appropriations in FY 2021 supported 116 full-time equivalents (FTEs), including salaries and operational expenses, to support OTC monograph drug activities. Detailed program accomplishments can be found in the FY 2021 OMUFA Performance Report.

Report Overview

A. Scope

This financial report addresses the implementation of the OMUFA program and use of OMUFA fees by the Food and Drug Administration (FDA or Agency) during fiscal year (FY) 2021 (specifically from March 26, 2021, through September 30, 2021). 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 2021 fee collections, carryover, obligations of user fees, and total costs of OTC monograph drug activities covered by OMUFA fees and non-user-fee appropriations. Since FY 2021 was the first year of the program, many of the OMUFA-related activities (such as refunds, carryover, and shared services) start from a zero point. In addition, the truncated time frame for assessing and collecting the annual FY 2021 OMUFA fees resulted in a shortened window between the collection and spending of user fees compared to other user fee programs.

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**.

Management Discussion

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 the 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 the public health by maximizing compliance of FDA-regulated products and by 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 OTC monograph drug user fee program from FY 2021 through FY 2025. This 5-year authorization provides user fee funding for FDA to support OTC 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.
	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. 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), operating reserve, additional direct costs, and additional dollar amounts. 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 Consolidated Appropriations Act, 2021 (Public Law 116-260), made appropriations through September 30, 2021, for the Salaries and Expenses account of FDA. It specified that fees relating to OTC monograph drugs authorized by 21 U.S.C. 379j–72 shall be credited to this 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 $12,000,000 multiplied by an adjustment factor applicable to the fiscal year involved. (The adjustment factor does not apply in FY 2021, the first year of the program.) 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 2021 is $12,000,000. In FY 2021, FDA obligated $28,084,322, exclusive of user fees, for the OMUFA program. As FDA spent more than the specified minimum amount in FY 2021, 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 agreed to commit to specified performance goals in terms of certain OTC monograph drug activities. 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 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 (GRASE) finalization OMORs

G. Performance Summary

Beginning in March 2020, FDA experienced the unexpected onset of a public health emergency, the impact of which continued throughout FY 2021. The COVID-19 pandemic resulted in a shift to 100 percent virtual work for the majority of the Agency's staff. The Agency appropriately shifted resources to prioritize work focused on addressing the pandemic. Despite this, FDA managed to achieve a considerable number of the FY 2021 OTC monograph reform objectives, which were supported with OMUFA user fees. Highlighted below are FDA's accomplishments supported by OMUFA in FY 2021:

- Submitted a letter to Congress describing FDA's progress in evaluating the cough cold monograph with respect to children under the age of 6
- Published a notice in the *Federal Register* (September 21, 2021; 86 FR 52474) announcing the availability of certain final administrative orders that were deemed established under the CARES Act (also known as "deemed final orders" or DFOs). These DFOs provide the current OTC monograph conditions for each therapeutic category addressed by a respective DFO, as of the date of enactment of the CARES Act. This notice also announced the process for making the DFOs available and announced plans for modifying the Agency's regulations in accordance with the OTC monograph reform authority enacted under the CARES Act.
- Created a new interim public-facing web portal, OTCMonographs@FDA, that provides a resource for the public to view proposed, final, and interim final orders for OTC monograph drugs. OTCMonographs@FDA also facilitates the submission of comments and data from the public for proposed and interim final administrative orders.
- Began posting DFOs on the new web portal, OTCMonographs@FDA.
- Posted the first annual monograph forecast on the new web portal, OTCMonographs@FDA.
- Issued the proposed order for sunscreen drug products for OTC use, published a notice of availability of such proposed order in the *Federal Register*, and alerted any potentially affected sponsors about the upcoming proposed order 2 days prior to its issuance.
- Issued a Request for Proposal to secure IT services in support of mandated technical requirements.
- Awarded a contract to provide IT services for development of a public facing monograph web portal.
- Engaged in sustained efforts to recruit and hire new talent for the OTC monograph reform program.
- Facilitated significant industry and public outreach on monograph reform.

FDA continues to work toward improving its performance in meeting or exceeding expectations in the implementation and completion of the performance goals established under OMUFA.

Financial Information

This section provides an overview of the program financials for OMUFA for FY 2021. These financials include user fee revenue, obligations, carryover, non-user-fee appropriations, and FTEs.

H. User Fee Program Financials

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

Table 1: OTC Monograph Drug Collections, Obligations, and Carryover for FY 2021

Budgetary Resources	Notes	FY 2021
Target Revenue	**Note 1**	**$23,269,000**
Total Carryover, Beginning of Year		$0
Net Collections		$20,103,265
Recoveries	Note 2	$0
Total Budgetary Resources		**$20,103,265**
Obligations	**Notes**	**FY 2021**
Total Payroll and Operating	Note 3	$6,946,337
Total Rent	Note 4	$0
Total Shared Services	Note 5	$0
Total Obligations		**$6,946,337**
Carryover	**Notes**	**FY 2021**
Total Carryover, End of Year		**$13,156,928**

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 (see section I).

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, operating reserve, additional direct costs, and additional dollar amounts. FDA has applied those factors in the target revenue for annual fee setting. See **Table 2**.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of 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 is provided in **Section K**.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for FY 2021. 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 Revenue and Collections Statement for FY 2021

Target Revenue	Notes	FY 2021
Base Amount		$8,000,000
Inflation Adjustment	Note 6	$0
Operating Reserve	Note 7	$1,269,231
Additional Direct Cost		$14,000,000
Target Revenue Total	Note 1	**$23,269,000**

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 is defined in the statute. The base amount for FY 2021 is specified in the statute and then adjusted for the following factors, if applicable: inflation, operating reserve, additional direct costs, and additional dollar amounts. For FY 2021, the annual target revenue was not adjusted for inflation but will be adjusted in FY 2022 and each subsequent year (see section 744M(c)(1) of the FD&C Act).

Section 744M(a) of the FD&C Act specifies that fees are to be collected for 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. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Cohort Year
The year in which user fee collections are originally due and reported. For example, a fee originally due in FY 2021 but received in FY 2022 is attributed to FY 2021 collections.

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. The funds carried over from year to year are described in **Section K – User Fee Carryover**.

Table 3 outlines the OMUFA collections by fee source and cohort year. Refer to **Section D** for more background and information on the OMUFA fee structure.

Table 3: OMUFA Collections by Fee Source for Cohort Year 2021

FEES COLLECTED	Cohort Year 2021		
	Target	Actual	% Diff
Facility Fees	$23,269,000	$20,098,284	-14%
OMOR Tier 1 Fees	$0	$0	N/A
OMOR Tier 2 Fees	$0	$0	N/A
Total Collections	**$23,269,0000**	**$20,098,284**	**-14%**

FEES RECEIVABLE	Actual 2021
Facility Fees	$9,273,780
OMOR Tier 1 Fees	$0
OMOR Tier 2 Fees	$0
Total Receivables	**$9,273,780**

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.

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 first fiscal year of the OMUFA program. The financial notes can be found in **Appendix E.**

Table 4: OMUFA Obligations by Expense Category for FY 2021

User Fee Obligations	Notes	FY 2021
Payroll & Operating	Note 3	
CDER		$6,946,337
ORA		$0
HQ		$0
Total Rent	Note 4	$0
Total Shared Services	Note 5	$0
Total Obligations		**$6,946,337**

Numbers have been rounded to the nearest dollar.

The OMUFA program obligated funds to support the hiring of full-time equivalents (FTEs) and the meeting of OMUFA commitments. 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 the OMUFA program.

- **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. Cost assessments for distributing rent costs were conducted prior to the start of OMUFA and were, therefore, considered $0 for FY 2021.

- **Shared Services:** FDA has several shared services organizations, such as human resources and IT, that provide support across the user fee programs. Cost assessments for distributing shared services costs were conducted prior to the start of OMUFA and were, therefore, considered $0 for FY 2021.

Table 5 provides the total amount spent by FDA, as well as by each major FDA component that supports the OMUFA program, in FY 2021.

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

Costs		FY 2021
Total Spent		**$35,030,659**
CDER	Spent	$24,880,226
	Percent	71%
ORA	Spent	$7,602,736
	Percent	22%
HQ	Spent	$2,547,697
	Percent	7%

Numbers have been rounded to the nearest dollar.

K. User Fee Carryover

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

Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under-collecting fees and the risk of a lapse in appropriations. In order to mitigate those risks in FY 2021, the OMUFA program was allowed to make adjustments specified in section 744M(c)(2) of the FD&C Act. In FY 2021, facility fees were due on May 10, 2021, and the bulk of the fees were received late in the fiscal year. 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 OMUFA 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 2021. The financial notes can be found in **Appendix E**.

Table 6: OMUFA Carryover for FY 2021

Carryover	Notes	FY 2021
Total Carryover, End of Year		**$13,156,928[2]**
OMUFA Continuity, Set Aside		($12,282,030)
Future Year Refunds Allowance, Set Aside	Note 9	($100,000)
Carryover Net of Set Aside, End of Year		**$774,898**

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.

[2] Although OMUFA carried this amount into FY 2022, the Agency must rely on these funds to sustain its OTC monograph drug activities until it collects the FY 2022 facility fees—the bulk of OMUFA collections—which are not due until June 2022. This third fiscal quarter due date for annual OMUFA fees is in contrast with PDUFA, GDUFA, and BsUFA, for which collections of annual fees are aligned with the start of the fiscal year.

Table 7: OTC Monograph Drug User Fee Collections, Obligations, and Carryover

Carryover	Notes	OMUFA
		FY 2021
Total Carryover, Beginning of Year		**$0**
Net Collections		$20,103,265
Recoveries	Note 2	$0
Total Obligations		($6,946,337)
Total Carryover, End of Year		**$13,156,928**

Numbers have been rounded to the nearest dollar.

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 budget authority spending trigger." The FY 2021 spending trigger is $12,000,000.

The non-user-fee budget authority (BA) 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 year, 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

Obligations		FY 2021
Total Obligated		**$35,030,659**
Non-User Fee Appropriations	Total	$28,084,322
	Percent	80%
User Fee Revenue	Total	$6,946,337
	Percent	20%

Numbers have been rounded to the nearest dollar.

M. Full-Time Equivalents

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

As they relate to OMUFA, FTEs are referred to as "Process FTEs." Process FTEs are how FDA measures a paid staff year devoted to the OMUFA program. In the table below, an FTE does not represent an accounting of individual people, but rather an FTE represents an estimate of labor hours expended on

OTC monograph drug activities. Funding is distributed to FDA's Centers based on the workload to support payroll to accomplish the program goals.

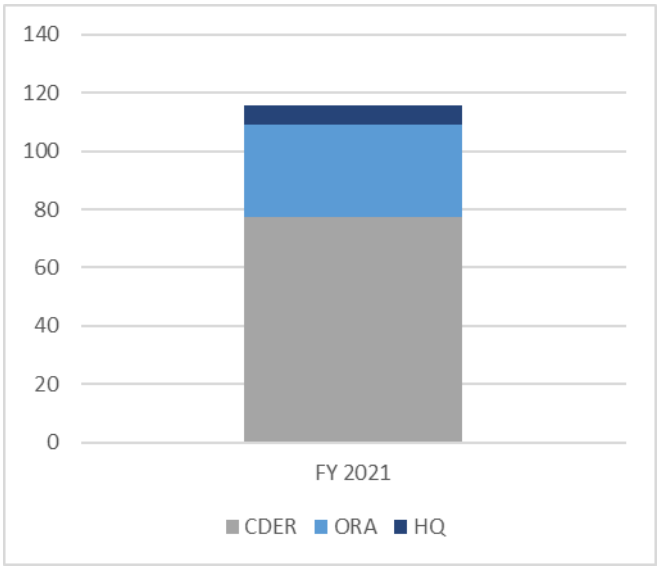
Table 9 presents total Process FTE levels, paid from user-fee and non-user-fee appropriations, that support the OMUFA program. The data are arranged by FDA's organizational components (CDER, ORA, and HQ). Staff in the consolidated shared services organizations (facilities, procurement, IT services, etc.)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

Organization	FY 2021
CDER	77
ORA	32
HQ	6
Total	**116**

Exhibit 4 provides the FTE distribution across FDA's organizations for the past year.

Exhibit 4: Total Process FTE Levels by FDA's Organizations



Management Assurance

N. Internal Controls

The Federal Managers' Financial Integrity Act of 1982 (FMFIA) is intended to strengthen internal controls and accounting systems. OMB Circular A-123, Management's Responsibility for Internal Control and

Enterprise Risk Management (OMB A-123), implements the FMFIA requirements. FMFIA requires that management establish and maintain effective internal control to achieve the following objectives:

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

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

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

Additionally, FDA has an established Senior Assessment Team (SAT) to act as the governance body responsible for providing oversight and accountability for FDA's internal control over reporting, including overseeing the FMFIA and OMB A-123 assessments, and for fostering an environment that promotes strong internal control. The SAT is chaired by FDA's CFO and co-chaired by the Deputy CFO and Director of the Office of Financial Management, as well as a Program Co-Chair who is a Center Deputy Executive Officer appointed by the CFO. The SAT members are representatives from each FDA Center and Office.

FDA's internal control program includes integrated management controls covering the OMB A-123 appendices. Specifically, reporting controls are implemented in accordance with Appendix A, Management of Reporting and Data Integrity Risk; charge card controls are implemented in accordance with Appendix B, A Risk Management Framework for Government Charge Card Programs; controls over financial disbursements are implemented in accordance with Appendix C, Requirements for Payment Integrity Improvement; and financial system controls are implemented in accordance with Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's reimbursable activity cycle memo is specifically focused on the reporting controls related to the accounts receivable and payment processes associated with the user fee programs. This cycle memo describes the processes and controls performed by FDA to monitor the user fee cash receipts process and includes

controls over reconciliation performance, aging, write-offs, and the interface between the User Fee System (UFS) and the Unified Financial Management System.

In FY 2021, FDA's annual assessment of internal controls included tests of 80 business, charge card, and IT controls across 18 transaction sub-cycles to identify recommendations to strengthen internal controls and compliance. This assessment included 27 IT controls related to the UFS. Annually, FDA conducts an improper payments risk assessment and performs improper payment testing. In March 2021, FDA completed this testing, which involved 100 payments related to user fee funding, including payments for vendors (64), purchase cards (16), grants (14), and travel (6). Any deficiencies identified during FDA's internal control testing are tracked under a Continuous Monitoring Program to facilitate timely remediation. UFS is compliant with HHS guidelines and with OMB Circular A-123 Appendix D, Compliance with the Federal Financial Management Improvement Act of 1996. FDA's Integrated Budget and Acquisition Planning System (IBAPS) not only is used to support FDA's budget formulation, budget execution, acquisition planning, and payroll planning but also meets FDA's and HHS's system requirements.

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 2021 HHS audit found that FDA's financial statements fairly present, in all material respects, the consolidated financial position of HHS as of September 30, 2021, and 2020, and related notes are in accordance with generally accepted accounting principles in the United States. Further, FDA's FY 2021 Assurance Statement found no material weaknesses or financial system nonconformances.

O. Risks and Challenges

Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some in FDA's control and some out of FDA's control. An example of a financial risk shared across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user-fee appropriations. FDA can only assume what the Agency's total appropriation will be in any given year. As a result, FDA has some risk of missing important performance goals, or failing to meet the non-user-fee BA 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 under-spent due to the uncertainty around the timing of revenue (user fee and non-user-fee) availability, non-user-fee spending trigger requirements, and difficulties with hiring. To minimize this risk, FDA will enhance its planning and execution around the hiring of new staff and contract actions in the second year of the program.

- **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 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 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. Actual collections were less than estimated collections in FY 2021.

- **Industry Familiarity with OMUFA Framework**: FDA is uncertain if the facilities that are assessed the OMUFA facility user fee will meet their user fee obligation due to an unfamiliarity with the OMUFA framework. As OMUFA is a relatively new user fee program, many OTC monograph drug manufacturers do not have the regulatory knowledge associated with mandated user fee obligations.

- **Global Health Pandemic:** There is 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 program in its inaugural year, such as with the OMUFA program, challenges will arise. A major challenge for the OMUFA program that occurred in FY 2021 was that many companies in the industry were unfamiliar with the new regulatory landscape and the financial obligations in manufacturing OTC monograph drug products under OMUFA.

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, including recommended annual fee revenues, FDA must provide the proposed recommendations to specified congressional committees and publish the recommendations in the *Federal Register*.

B. Allowable and Excluded Costs for the OMUFA Program

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 OTC monograph order requests, 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 inspection 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. Postmarket 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 below provides the details regarding each legal condition contained in the applicable sections of the FD&C Act.

Exhibit 5: 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 (also described in **Section L** above), 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 2021, the spending trigger amount is $12,000,000 because the applicable adjustment factor described above does not start until FY 2022.

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, operating reserve, additional direct costs, and additional dollar amounts).

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

Payroll and operating costs associated with OTC monograph drug activities are based on obligations attributed to CDER, ORA, and HQ. These costs relate to how much of the OMUFA revenue is going toward payroll and operating expenses.

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support 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 contains several shared service organizations that provide support across the user fee programs. The shared service organizations include the following:

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: Provides support to all FDA employees requesting administrative, IT, facilities, human resources, and other employee services.
- **Office of Acquisitions and Grants Services**: Manages contracts, grants, and other agreements.
- **Office of Equal Employment Opportunity**: Promotes an inclusive work environment that ensures equal employment opportunity and fosters a culture that values diversity and empowers individuals.
- **Office of Facilities, Engineering, and Mission Support Services**: Provides FDA's employees with office and laboratory facilities.
- **Office of Financial Management:** Provides financial managerial services and policy guidance.
- **Office of Information Management and Technology**: Provides the information, communication, and knowledge infrastructure and services that enhance, transform, and sustain the ability of FDA to protect and promote the public health.
- **Division of Budget Execution and Control:** Initiates, monitors, and analyzes FDA's budget resources. The Agency's budget is composed of several appropriation accounts, including

Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.

- **Office of External Affairs – History:** Provides research, documentation, and preservation of significant FDA historical resources and serves as historian for the Agency.
- **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's safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through the development and implementation of administrative policies, programs, and initiatives.
- **Program Alignment Team:** Provides advice and guidance on reorganizations and delegations of authority.
- **Office of Human Capital Management:** Provides human resources 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.

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. An adjustment for inflation was not utilized in FY 2021 because the adjustment for inflation does not apply until FY 2022 (see section 744M(c)(1) of the FD&C Act).

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 2021 facility fee revenue and fees if such an adjustment is necessary in order to provide up to 3 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 applied the operating reserve adjustment to increase the FY 2021 facility fee revenue and fees to enable the Agency to maintain 3 weeks of operating reserves of carryover user fees. To determine the 3-week operating reserve amount, the FY 2021 annual base revenue adjusted for additional direct costs (i.e., $8,000,000 + $14,000,000 = $22,000,000), is divided by 52, and then multiplied by 3. The 3-week operating reserve amount for FY 2021 is $1,269,231.

Note 8. Additional Direct Costs Adjustment

Under OMUFA, $14,000,000 is added to the facility fee revenues for FY 2021 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 OTC monograph order request 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.