FY 2021

FINANCIAL REPORT TO CONGRESS

for the

Animal Generic Drug User Fee Act

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Executive Summary

The Animal Generic Drug User Fee Act of 2008 (AGDUFA), as amended, requires the Food and Drug Administration (FDA) to report to Congress annually on the financial aspects of AGDUFA implementation. This is the third report under the third authorization of AGDUFA (AGDUFA III) and covers fiscal year (FY) 2021.

AGDUFA III specifies that the following three legal conditions must be satisfied each year for FDA to collect and spend AGDUFA user fees:

1. FDA's overall Salaries and Expenses appropriation, excluding fees, must meet or exceed FDA's overall FY 2003 Salaries and Expenses appropriation, excluding fees and multiplied by an adjustment factor specified in the statute.

2. The fee amounts FDA can collect must be provided in appropriation acts.

3. FDA must spend at least as much from appropriated funds for the review of generic new animal drug applications as it spent in FY 2008, multiplied by an adjustment factor specified in the statute.

FDA met the three legal conditions in FY 2021, and this report explains how these legal conditions were satisfied. The statements and tables in this report provide data on generic new animal drug user fee collections, expenditures, and carryover, as well as comparative data from prior fiscal years.

In FY 2021, FDA had net collections of $29 million in AGDUFA fees, spent $21 million in user fees for the process for the review of abbreviated applications for generic new animal drugs, and carried $31 million forward for future fiscal years.

AGDUFA user fees and non-user fee appropriations in FY 2021 supported 128 full-time equivalents, including salaries and operational expenses, to support the process for the review of generic new animal drug abbreviated applications. Detailed program accomplishments can be found in the FY 2021 AGDUFA Performance Report.

Report Overview

A. Scope

This financial report describes the collection and use of generic new animal drug user fees by the Food and Drug Administration (FDA or Agency) during the period from October 1, 2020, through September 30, 2021. It specifies the legal conditions that FDA must satisfy each year to collect and spend Animal Generic Drug User Fee Act (AGDUFA) fees and documents how FDA determined that it met those requirements for fiscal year (FY) 2021. In addition, this report presents summary statements of FY 2021 fee collections, carryover, obligations of user fees, and total costs of the process for the review of abbreviated applications for generic new animal drugs.

B. Report Requirements

In accordance with section 742(b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act), FDA will submit to Congress an annual financial report on the implementation of FDA's authority for user fees during the fiscal year for which the report is made and the use by the Agency of the fees collected for such fiscal year. The purpose of this report is to meet these requirements for FY 2021.

FDA is required to submit the financial report to Congress no later than 120 days after the end of each fiscal year. FDA also must make the report available to the public on its Internet website. Additional details on the reporting requirements 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 by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public health by helping to speed innovations that make medical products more effective, safe, and affordable and by helping the public get accurate, science-based information needed to use medical products and to consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability. FDA fulfills this responsibility by ensuring the security of the food supply and by fostering development of medical products to respond to deliberate and naturally emerging public health threats.

The Center for Veterinary Medicine (CVM) is responsible for regulating animal drugs, veterinary devices, and food for animals. CVM evaluates new animal drug applications for safety and effectiveness; monitors animal drugs, foods, and devices on the market; evaluates animal food additives for safety and utility; and conducts applied research to further protect human and animal health. CVM also helps promote and provide incentives for the availability of animal drugs to meet the needs of the large number and wide diversity of minor species, such as fish, honey bees, and birds, and for minor uses (infrequent and limited) in the major species: cattle, pigs, chickens, dogs, cats, horses, and turkeys. In

furtherance of this Agency's mission to promote and protect the health of humans and animals, CVM also takes steps to help facilitate access to safe, effective, and innovative products, including animal food products, that can address existing, novel, and emerging animal health challenges.

Program Organization

There are three major FDA components that support the AGDUFA program: CVM, 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
CVM	CVM protects and promotes the health of humans and animals from a One Health perspective by helping to ensure the safety of the American food supply, the safety of animal food and devices, and the safety and effectiveness of animal drugs.
ORA	ORA protects consumers and enhances the public health by maximizing the compliance of FDA-regulated products and minimizing the risk associated with those products.
HQ	HQ provides FDA-wide program direction and administrative services to ensure FDA programs are effective and efficient.

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 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 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

The FD&C Act, as amended by AGDUFA, authorizes FDA to collect fees from industry to supplement non-user fee appropriations that the Agency spends on the process for the review of abbreviated applications for generic new animal drugs.

The Animal Drug and Animal Generic Drug User Fee Amendments of 2018 includes the reauthorization of AGDUFA, also known as AGDUFA III, which extends the AGDUFA program from October 1, 2018, through September 30, 2023. This 5-year reauthorization provides continued funding for FDA from FY

2019 through FY 2023 to support program operations, evaluation, and improvement. AGDUFA III continues to deliver tremendous public health benefits by enhancing FDA's capacity to review generic new animal drug submissions to help ensure that products coming to the market for the American public will be safe and effective.

FDA spends AGDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for the review of generic new animal drug abbreviated applications.

AGDUFA III establishes a fee structure comprised of the following three types of fees: application fee, product fee, and sponsor fee.

Exhibit 2 outlines the types of user fees under AGDUFA III.

Exhibit 2: AGDUFA III Fee Types

Fee Type	Definition
Application (Section 741(a)(1) of the FD&C Act)	Each person that submits an abbreviated application for a generic new animal drug shall be subject to an abbreviated application fee. The terms "abbreviated application for a generic new animal drug" and "abbreviated application" mean an abbreviated application for approval of any generic new animal drug submitted under section 512(b)(2) of the FD&C Act, except that the terms do not include a supplemental abbreviated application for a generic new animal drug. An abbreviated application subject to the criteria in section 512(d)(4) of the FD&C Act shall be subject to 50 percent of the abbreviated application fee applicable to all other abbreviated applications for generic new animal drugs.
Product (Section 741(a)(2) of the FD&C Act)	Each person named as the applicant in an abbreviated application or supplemental abbreviated application for a generic new animal drug product submitted for listing under section 510 of the FD&C Act and who had an abbreviated application or supplemental abbreviated application pending at FDA after September 1, 2008, shall pay an annual fee for each such generic new animal drug product.
Sponsor (Section 741(a)(3) of the FD&C Act)	The sponsor fee must be paid annually by each person who: (1) is named as the applicant in an abbreviated application that has not been withdrawn by the applicant and for which approval has not been withdrawn by FDA or has submitted an investigational submission for a generic new animal drug that has not been terminated or otherwise rendered inactive by FDA; and, (2) had an abbreviated application for a generic new animal drug, a supplemental abbreviated application for a generic new animal drug, or an investigational submission for a generic new animal drug pending at FDA after September 1, 2008. A generic new animal drug sponsor is subject to only one such fee each fiscal year. Applicants with more than six approved abbreviated applications pay 100 percent of the sponsor fee; applicants with more than one and fewer than seven approved abbreviated applications pay 75 percent of the sponsor fee; and applicants with one or fewer approved abbreviated applications pay 50 percent of the sponsor fee.

Section 741(b) of the FD&C Act establishes the total revenue amounts from fees for each fiscal year of AGDUFA III. It also specifies the percentage of the total revenue amounts to be derived from each type of user fee: application fees (25 percent), product fees (37.5 percent), and sponsor fees (37.5 percent).

The statute specifies at section 741(c) of the FD&C Act how the fees are to be calculated each fiscal year, including annual adjustments that must be made for inflation, beginning with FY 2020. The statute also provides for the possibility of annual adjustments because of changes in FDA's workload related to the process for the review of abbreviated applications for generic new animal drugs, also beginning with FY

2020. FDA publishes the fee amounts, and the methodology it used to calculate these amounts, in the *Federal Register* each year.[1]

AGDUFA user fees are not a fee-for-service. Instead, the user fees that are collected are pooled together and may be used for any of 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 background information on the AGDUFA user fee program.

E. Legal Conditions

The FD&C Act, as amended by AGDUFA, specifies three legal conditions that must be satisfied each year for FDA to collect and spend generic new animal drug user fees. **Exhibit 3** describes those legal conditions and provides a brief explanation as to how those legal conditions were met for FY 2021.

Exhibit 3: AGDUFA Legal Conditions

Legal Condition #	Details	
1	Description	FDA's overall Salaries and Expenses appropriation (excluding user fees) for the fiscal year at issue must meet or exceed the amount of FDA's FY 2003 Salaries and Expenses appropriation (excluding user fees), multiplied by an adjustment factor specified in the statute. [Section 741(f)(1) of the FD&C Act].
	Met	In FY 2021, FDA's Salaries and Expenses appropriation, excluding user fees, was $3,201,928,000. FDA's FY 2003 Salaries and Expenses appropriation, excluding user fees, was $1,949,915,590 after applying the adjustment factor. Therefore, the first legal condition was satisfied.
2	Description	The amount of user fees FDA may collect for each fiscal year must be specified in that year's appropriation acts. [Section 741(g)(2)(A)(i) of the FD&C Act].
	Met	Division A, Title VI of Public Law 116-260 specified that $22,797,000 shall be derived from generic new animal drug user fees and that generic new animal drug user fees collected in excess of this amount are appropriated for FDA. Therefore, the second legal condition was satisfied.
3	Description	User fees may be collected and used only in years when FDA spends a specified minimum amount of appropriated funds (exclusive of user fees) for the review of generic new animal drug applications. This specified minimum is the amount FDA spent on the process for the review of abbreviated applications for generic new animal drugs from appropriations (exclusive of user fees) in FY 2008, multiplied by an adjustment factor specified in the statute. [Section 741(g)(2)(A)(ii) of the FD&C Act]. Under AGDUFA, this condition is considered met if the total review expense funded by appropriations in any fiscal year is no more than three percent below the specified minimum. [Section 741(g)(2)(B) of the FD&C Act].
	Met	The specified minimum level for FY 2021 is $6,786,656. In FY 2021, FDA obligated $9,437,145 from appropriations (exclusive of user fees) for the process for the review of abbreviated applications for generic new animal drugs. Because FDA spent more than the specified minimum amount from appropriations in FY 2021, the third legal condition was satisfied.

[1] See https://www.federalregister.gov/documents/2020/08/03/2020-16688/animal-generic-drug-user-fee-rates-and-payment-procedures-for-fiscal-year-2021.

The legal conditions as stated in the FD&C Act and details on the adjustment factors are included in **Appendix D.**

F. Strategic Plan

FDA is focused on utilizing AGDUFA user fee and non-user fee appropriations to achieve the performance goals and program enhancements outlined in the AGDUFA III Performance Goals and Procedures.[2]

G. Performance Summary

FDA exceeded the performance goals in the first 2 years of AGDUFA III. FDA met the review-time goals in 379 of 396 submissions. The entire FY 2020 cohort has closed; therefore, there are no pending submissions.

As of September 30, 2021, preliminary performance data were available for 235 of 501 submissions filed in FY 2021. FDA is currently exceeding all performance goals. Overall, FDA met review-time goals for 226 of 235 submissions acted on. With 266 submissions pending within goal, FDA has the potential to meet or exceed the performance goals for all five of the submission types in FY 2021. Please refer to the FY 2021 AGDUFA Performance Report for more information.

Financial Information

This section provides an overview of the program financials for AGDUFA for FYs 2020 and 2021. These financials include user fee revenue, obligations, carryover, non-user fee appropriations, and full-time equivalents (FTEs).

H. User Fee Program Financials

Table 1 represents a summary of the AGDUFA user fee financial position for FY 2020 and FY 2021. The financial notes referenced in this table can be found in **Appendix E**.

Table 1: Animal Generic Drug Resources, Obligations, and Carryover for FYs 2020 and 2021

Budgetary Resources	Notes	FY 2020	FY 2021
Target Revenue		**$20,151,000**	**$22,796,000**
Total Carryover, Beginning of Year		$14,924,330	$22,749,744
Net Collections		$24,089,530	$28,839,856
Recoveries	Note 1	$44,535	$137,313
Total Budgetary Resources		**$39,058,395**	**$51,726,913**

[2] For more details, see Animal Generic Drug User Fee Act Reauthorization Performance Goals and Procedures – Fiscal Years 2019 Through 2023 at https://www.fda.gov/media/116328/download.

Obligations	Notes	FY 2020	FY 2021
Total Payroll and Operating	Note 2	$14,022,954	$17,851,046
Total Rent	Note 3	$499,123	$425,400
Total Shared Services	Note 4	$1,786,574	$2,302,841
Total Obligations		**$16,308,651**	**$20,579,287**

Carryover	Notes	FY 2020	FY 2021
Total Carryover, End of Year		**$22,749,744**	**$31,147,626**

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 and additional user fee collections). The "Target Revenue" is the total revenue amount set out in section 741(b)(1) of the FD&C Act (statutory fee revenue amount), after adjustment for inflation and/or workload when applicable. The target revenue amount is determined as part of the process of setting fee rates for the fiscal year. "Net Collections" are the actual amounts collected during the fiscal year.

AGDUFA III specifies how the fees must be calculated each fiscal year, including annual adjustments to revenue amounts that must be made for inflation for FY 2020 through FY 2023. After the applicable inflation adjustment to fees is done, FDA may further increase the fee revenue amounts to reflect changes in workload for FY 2020 through FY 2023. For FY 2021 through 2023, if fee revenue is increased to reflect changes in workload, the increase may be reduced by the amount of any excess collections for the second preceding fiscal year, up to the full amount of the workload-based fee revenue increase. However, the reduction for excess collections cannot result in fee revenue for a fiscal year that are less than the inflation-adjusted amount originally calculated.

Obligations: The "Obligations" component of **Table 1** shows the annual expenditure of AGDUFA fee funds broken out into major expense categories. AGDUFA fees may be expended only for costs to support the "process for the review of abbreviated applications for generic new animal drugs," as defined in AGDUFA III.

Carryover: AGDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the AGDUFA program in future fiscal years. In this report, such fee funds, plus certain user fee funds that FDA has collected that are considered unappropriated, are referred to as the "total carryover" or the "AGDUFA 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 financial challenges associated with a lapse in appropriations, so that FDA can continue performing reviews of abbreviated applications for generic new animal drugs under these financial constraints. When setting fees for the final fiscal year of AGDUFA III, FDA is authorized to increase fees, if necessary, to provide for up to 3 months of carryover at the end of FY 2023 (operational reserve) to sustain operations for the first 3 months of FY 2024. See **Section K** for more information on carryover and the operational reserve.

I. User Fee Revenue

Table 2 outlines the annual target revenue amounts for each fiscal year. These amounts are used to establish the AGDUFA fee rates for each fiscal year. The financial notes referenced in this table can be found in **Appendix E.**

Table 2: Generic New Animal Drug Target Revenue and Collections Statement for FYs 2020 and 2021

Target Revenue	Notes	FY 2020	FY 2021
Statutory Fee Revenue Amount		$18,336,340	$18,336,340
Inflation Adjustment	Note 5	$416,327	$657,303
Workload Adjustment	Note 6	$1,398,161	$5,381,526
Reduction of Workload Adjustment by Excess Fees	Note 6	N/A	($1,579,201)
Target Revenue Total		**$20,151,000**	**$22,796,000**

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

The process for adjusting the statutory fee revenue amount for inflation and/or workload, when applicable, to calculate the annual target revenue amount that will be used to set the fee rates for each FY is described in the statute. Using the target revenue amount, FDA calculates the fee rates for the fiscal year and publishes the rates in the *Federal Register*.

AGDUFA authorizes FDA to collect application fees, product fees, and sponsor fees. User fee collections are recognized and reported in the year the fee was originally due (referred to as the "cohort year"). Totals reported for each fiscal year are net of any refunds for the cohort year. To ensure the quality of the information provided in this financial report, FDA annually updates the prior years' numbers.

Cohort Year

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

Increase in Collections

The primary factor in the increase in collections was an increase in application fees received in FY 2021.

Table 3 outlines AGDUFA collections by fee source and cohort year.

Table 3: Generic New Animal Drug User Fee Collections by Fee Type for Cohort Years 2020 and 2021

Fees Collected	Cohort Year 2020			Cohort Year 2021		
	Estimated†	Actual	% Dif.	Estimated††	Actual	% Dif.
Application Fees	$5,037,750	$7,902,337	57%	$5,699,000	$11,038,595	94%
Product Fees	$7,556,625	$9,054,862	20%	$8,548,500	$8,445,123	-1%
Sponsor Fees	$7,556,625	$7,280,915	-4%	$8,548,500	$7,815,322	-9%
Total Collections	**$20,151,000**	**$24,238,114**	**20%**	**$22,796,000**	**$27,299,040**	**20%**

Fees Receivable	FY 2020	FY 2021
Application Fees	$0	$0
Product Fees	$0	$0
Sponsor Fees	$86,165	$201,686
Total Receivables	**$86,165**	**$201,686**

Numbers have been rounded to the nearest dollar.
† Estimated values were taken from the generic new animal drug user fee rates for FY 2020.[3]
†† Estimated values were taken from the generic new animal drug user fee rates for FY 2021.[4]

J. User Fee Obligations

AGDUFA fees may be expended only for costs to support the "process for the review of abbreviated applications for generic new animal drugs," as defined in AGDUFA III. For more information on the allowable and excluded costs, see **Appendix B.**

Table 4 provides a comparison breakout of user fee obligations by expense category during the past 2 fiscal years. The financial notes can be found in **Appendix E**.

Table 4: Generic New Animal Drug User Fee Obligations by Expense Category for FYs 2020 and 2021

User Fee Obligations	Notes	FY 2020	FY 2021
Payroll & Operating	Note 2		
CVM		$13,406,436	$17,182,604
ORA		$0	$0
HQ		$616,518	$668,442
Total Rent	Note 3	$499,123	$425,400
Total Shared Services	Note 4	$1,786,574	$2,302,841
Total Obligations		**$16,308,651**	**$20,579,287**

Numbers have been rounded to the nearest dollar.

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

- **Payroll and Operating:** These obligations provide for all payroll and operating costs that support the allowable activities for which AGDUFA fees may be expended, as set forth in the statute. Such payroll and operating activities include, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, scientific activities, and management and administrative functions that support the AGDUFA program.
- **Rent:** This amount is paid to the General Services Administration (GSA) for the federal buildings that FDA occupies, as well as to non-federal sources for direct leases and services. Rent is charged at different rates depending on the type and location of the space provided.

[3] https://www.govinfo.gov/content/pkg/FR-2019-08-02/pdf/2019-16433.pdf.

[4] https://www.govinfo.gov/content/pkg/FR-2020-08-03/pdf/2020-16688.pdf.

- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT.

For historical context, **Table 5** provides the total amount spent by FDA and by each FDA organization on the AGDUFA program for the past 5 years, including both user fee and non-user fee appropriation obligations. As illustrated by the table, costs have increased over time and the percentage spent by each FDA organizational component has remained steady.

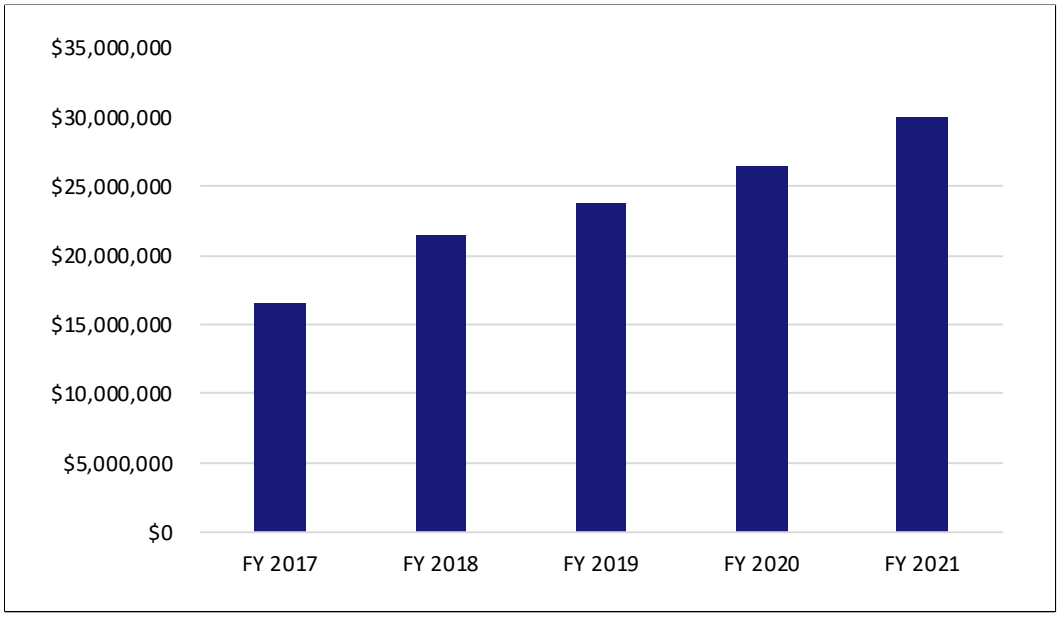
Table 5: AGDUFA Program – Historical Trend of Total Costs by Organization as of September 30 of Each Fiscal Year

Costs		FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Total Spent		**$16,605,270**	**$21,474,259**	**$23,827,759**	**$26,369,540**	**$30,016,432**
CVM	Spent	$14,819,138	$19,293,437	$21,239,206	$23,859,475	$27,315,733
	Percent	89%	90%	89%	90%	91%
ORA	Spent	$198,813	$481,508	$293,381	$193,356	$159,534
	Percent	1%	2%	1%	1%	1%
HQ	Spent	$1,587,319	$1,699,314	$2,295,172	$2,316,708	$2,541,166
	Percent	10%	8%	10%	9%	8%

Numbers have been rounded to the nearest dollar.

Exhibit 4 below provides an illustration of the combined historical AGDUFA costs for CVM, ORA, and HQ for the past 5 fiscal years.

Exhibit 4: Historical Total Costs by Fiscal Year



As demonstrated by this graph, there was a significant increase in AGDUFA program expenditures over the last 5 years. This increase was largely driven by adjustment for significant increase in workload.

K. User Fee Carryover

AGDUFA fees collected, appropriated, and not obligated at the end of the fiscal year, remain available to FDA 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 fee amounts and the risk of a lapse in appropriations. FDA considers a reasonable range of carryover for the AGDUFA program to maintain in anticipation of these risks to be about 20 weeks. FDA notes this reasonable range is higher for AGDUFA than for some other FDA user fee programs. This is because AGDUFA is a much smaller program, as measured by workload or planned expenditures, and small shifts in submission numbers could have a significant impact on workload and the requisite funding needed to maintain operations.

The net change in carryover each year is equal to net collections minus total obligations. This is demonstrated best in **Table 1** on Page 9.

Table 6 provides the AGDUFA carryover at the end of FY 2021. The financial note can be found in **Appendix E.**

Table 6: AGDUFA Carryover for FY 2021

Carryover	Notes	FY 2021
Total Carryover, End of Year		**$31,147,626**
Unappropriated Amounts		($2,363,711)
Future Year Refunds Allowance, Set Aside	Note 7	($100,000)
Operational Reserve, Set Aside		($6,199,500)
Carryover Net Unavailable and Set Aside, End of Year		**$22,484,415**

Numbers have been rounded to the nearest dollar.

These terms are definedbelow:

- **Total Carryover, End of Year –** This is the total amount of unobligated fee funds at the end of the fiscal year.
- **Unappropriated Amounts -** FDA's AGDUFA carryover includes $2,363,711 in fee collections that are considered unappropriated and therefore currently unavailable for obligation. This amount is the cumulative total of fee collections that exceeded the annual level of AGDUFA fees appropriated for a given year, prior to a technical fix that was added to the appropriations language to ensure that all fee collections would be considered appropriated.
- **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 7** for additional details.
- **Operational Reserve, Set Aside –** In FY 2023, FDA has the authority to hold up to 3 months (12 weeks) of operating reserves for the process for the review of abbreviated applications for generic new animal drugs for the beginning of FY 2024.

- **Carryover Net of Unavailable and Set Aside, End of Year –** This is the total carryover, less any carryover funds subject to set asides or subject to any restrictions that currently preclude FDA from obligating the carryover funds.

The operations in FY 2021 resulted in a net increase of the total carryover of $8,397,882, from $22,749,744 at the end of FY 2020 to $31,147,626 at the end of FY 2021. The primary driver for the increase in the carryover was the overall increase in net collections. For the AGDUFA program, user fee expenditures have steadily increased from FY 2019 to FY 2021, and CVM anticipates that these expenditures will continue to increase in FY 2022 as the program spends additional resources to continue meeting performance goals and the increased workload. Additionally, approximately $4.5 million was collected in excess of the FY 2021 target revenue due to an increase in applications received, as demonstrated in Table 3. These excess collections will likely result in a reduction of the workload-based increase in the fee revenue amount anticipated for FY 2023. The $4.5 million in excess collections is currently captured in the carryover. However, if a workload adjuster is invoked in FY 2023, the excess collections (or a portion of them) will be used to reduce the increase in the workload-based fee revenue amount. This scenario occurred during the FY 2021 fee-setting, when $1,579,201 in excess fees collected during FY 2019 was used to reduce the workload-based increase to the target fee revenue amount for FY 2021. (See Table 2.)

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

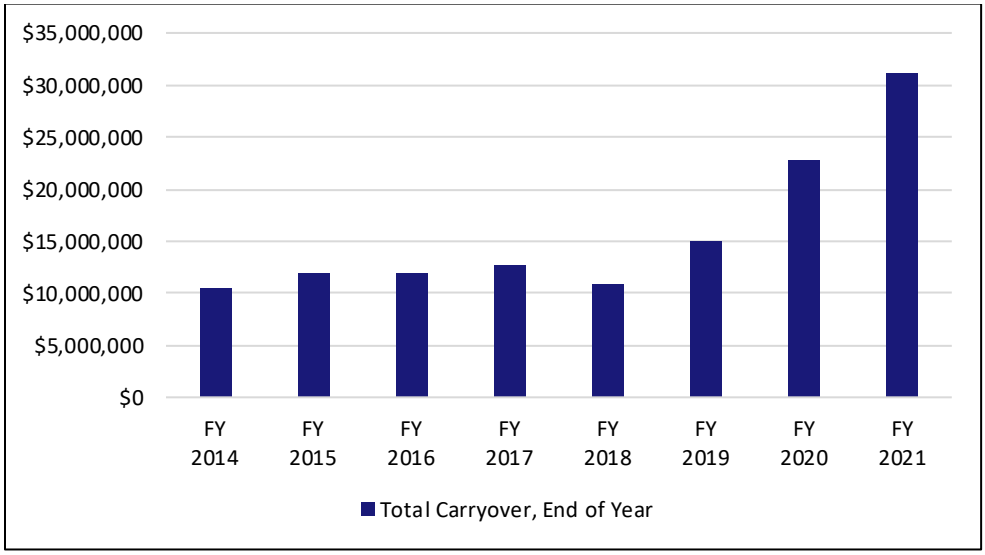
Table 7: Historical Generic New Animal Drug User Fee Collections, Obligations, and Carryover by Reauthorization Period

Carryover	Notes	AGDUFA I FY 2009 2013	AGDUFAIII FY 2014 2018	AGDUFA III FY 2019	AGDUFA III FY 2020	AGDUFA III FY 2021
Total Carryover, Beginning of Year		**$0**	**$8,546,799**	**$10,800,810**	**$14,924,330**	**$22,749,744**
Net Collections		$29,641,950	$48,190,167	$18,775,214	$24,089,530	$28,839,856
Recoveries	Note 1	$0	$203,538	$237,044	$44,535	$137,313
Total Obligations		($21,095,151)	($46,139,693)	($14,888,738)	($16,308,651)	($20,579,287)
Total Carryover, End of Year		**$8,546,799**	**$10,800,810**	**$14,924,330**	**$22,749,744**	**$31,147,626**

Numbers have been rounded to the nearest dollar.

Exhibit 5 provides a historical perspective of carryover for the last 8 fiscal years. FY 2018 shows a decrease in the carryover as the funds that had been held for the AGDUFA II final year offset were used to reduce the FY 2018 AGDUFA fee amounts, as authorized by AGDUFA II. The offset provision was removed for AGDUFA III in favor of a provision allowing the reduction of any workload-based increase by the amount of certain excess collections in FY 2021 through FY 2023. There was approximately $4.5 million in excess collections in FY 2021, due to an increase in applications received, which will likely result in a reduction of the workload-based increase in fee revenue amount anticipated for FY 2023. Therefore, the $8.4 million increase in carryover in FY 2021 can be divided into $4.5 million in excess collections, which are likely to be used to reduce a workload-based increase to the target fee revenue amount for FY 2023, and $3.9 million in additional carryover. FDA continues to increase user fee obligations as demonstrated by **Table 4**. This growth of the carryover is being driven by the workload adjuster.

Exhibit 5: Historical Carryover by Fiscal Year



L. Non-User Fee Appropriations

For FDA to obligate user fees collected under AGDUFA, a certain minimum amount of non-user fee appropriations must be spent on the process for the review of generic new animal drug applications during that fiscal year. This is often referred to as a "non-user fee spending trigger." (See Legal Condition 3 in Exhibit 3). The non-user fee spending trigger was $6,786,656 for FY 2021.

The "non-user fee spending trigger amount" is the amount of non-user fee appropriations spent on the generic new animal drug review process in FY 2008 ($5,510,000), multiplied by the adjustment factor. See **Note 8** for more details on the adjustment factor.

Table 8 provides the total amount spent on the AGDUFA program for the past 5 fiscal years and the dollar amount and percentages derived from user fee collections and non-user fee appropriations. The percentages attributable to AGDUFA fees have generally increased over time.

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

Obligations		FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
Total Obligated		**$16,605,270**	**$21,474,259**	**$23,827,759**	**$26,369,540**	**$30,016,432**
Non-User Fee Appropriations	Total	$6,245,725	$9,458,110	$8,939,021	$10,060,889	$9,437,145
	Percent	38%	44%	38%	38%	31%
User Fee Funds	Total	$10,359,544	$12,016,150	$14,888,738	$16,308,651	$20,579,287
	Percent	62%	56%	62%	62%	69%

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 No. A-11, section 85, means 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 AGDUFA, an FTE is referred to as a "Process FTE," which is the measure of a paid staff year devoted to the AGDUFA program. In the table below, an FTE does not represent an accounting of individual people but rather an estimate of labor hours expended on AGDUFA activities. Funding is distributed to Centers based on the workload to support payroll to accomplish the program goals.

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

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

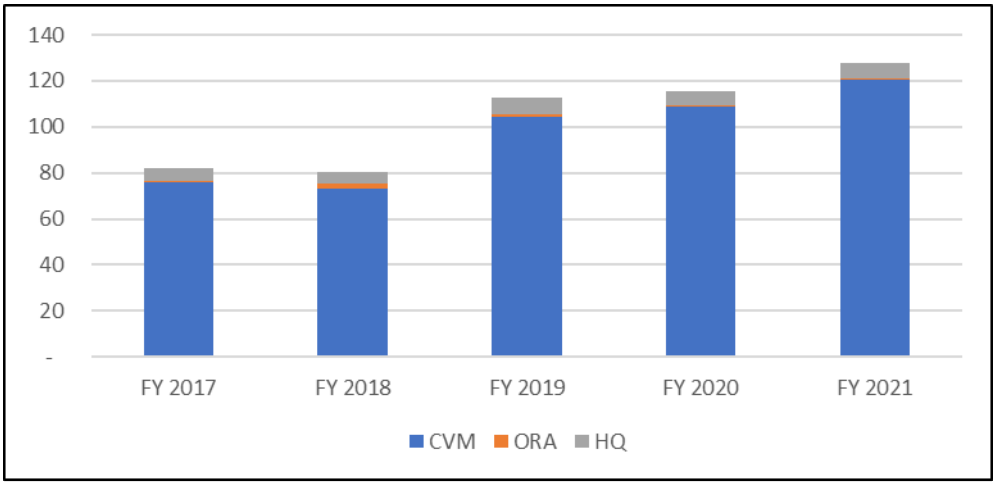
Fiscal Year	FY 2017	FY 2018	FY 2019	FY 2020	FY 2021
CVM	76	73	104	109	121
ORA	1	2	1	1	1
HQ	5	5	7	6	6
Total	**82**	**80**	**112**	**116**	**128**

Numbers have been rounded to the nearest whole number.

Exhibit 6 provides the historical trend of total Process FTE levels for AGDUFA across CVM, ORA, and HQ for the past 5 fiscal years. AGDUFA III allowed for a significant increase in FTEs beginning in FY 2019 to support reduced review time performance goals. As the workload has continued to increase, additional

FTEs have been supporting the generic premarket review program, resulting in an increase in CVM's FTEs in FY 2021.

Exhibit 6: Historical Total Process FTE Levels by FDA Organization



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 information technology (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 being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds, either through appropriated user fee collections or non-user fee appropriations. FDA can assume only 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 spending trigger for the fiscal year if that total appropriation comes in 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 in order to help move forward in the best interest of the program.

- **Uncertainty of User Fee Collections and 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 a good portion of the fiscal year. This is because of prolonged Continuing Resolutions (CRs), versus enactment of annual appropriations bills early in the fiscal year. Fluctuations in industry submissions from year to year can change the total program collections. This creates a situation where, because of extended CR periods, FDA is uncertain of its non-user fee appropriations for a significant portion of the fiscal year, yet it must still meet the non-user fee spending trigger.

- **Lapse in Non-User Fee Appropriations:** FDA is mitigating this risk to the program by maintaining a certain level of AGDUFA fees collected as a carryover. FDA considers a reasonable range of carryover for the AGDUFA program to maintain in anticipation of these risks to be about 20 weeks. FDA notes this reasonable range is higher for AGDUFA than for some other FDA user fee programs. This is because AGDUFA is a much smaller program, as measured by workload or planned expenditures, and small shifts in submissions could have a significant impact on workload and the requisite funding needed to maintain operations. This reserve can be used to help support program operations in the event of a shutdown.

- **Under-Executing Planned Spending:** Historically, AGDUFA user fee budgetary resources have been under-spent because of the uncertainty of revenue (user fee and non-user fee) and non-user fee spending trigger requirements. To minimize this risk, FDA worked with Congress on a non-user fee appropriation increase in FY 2017 and FY 2018 to alleviate some of the challenges meeting the spending trigger requirement.

- **Under-Collecting and Over-Collecting Fees:** If FDA does not receive the estimated number of industry submissions, there may be an excess or deficit in net collections as compared to the target revenue. When FDA under-collects user fees, it leverages its carryover to maintain continuity in operations. If FDA over-collects in FY 2019 through FY 2021, the excess collections will be used to reduce any increases in fee revenue resulting from workload-based adjustments in FY 2021 through FY 2023, up to the amount of the fee revenue increase. FDA monitors

collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when the user fee collection deviates from forecasted estimates.

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 decisions about the best use of its resources.

Strategic Challenges

In FY 2022, FDA will spend user fees to continue enhancing the generic new animal drug review process, focusing on improving the efficiency, quality, and predictability of the program. Some challenges FDA faces in FY 2022 include it's continued support of an all-electronic review environment, responding to an expanded workload due to increases in the volume of submissions, and meeting the challenges associated with the COVID-19 pandemic.

In response to challenges associated with COVID-19, CVM is applying flexibilities to its normal processes. For animal drug shortages caused by supply chain disruptions due to COVID-19, CVM worked with sponsors to prevent and mitigate shortages for all products and expedited the review of certain submissions for medically necessary veterinary products. Although these actions impacted review timelines for other pending submissions, CVM does not anticipate missing its overall user fee goals. In addition, CVM experienced delays in approving applications due to the continued challenges associated with conducting in-person pre-approval inspections, as reported in the FDA Resiliency Roadmap.[5] For bioequivalence trials, CVM continues to work with sponsors with impacted studies to ensure the safety of animals, their owners, and study personnel, to maintain compliance with good laboratory practice regulations, and to maintain the scientific integrity of the data. CVM also continues to assess the impacts of COVID-19 on preapproval and bioresearch monitoring inspections, including working with sponsors, when appropriate, to obtain information from alternate sources to minimize the impact of inspectional limitations on generic new animal drug approvals.

[5] See Resiliency Roadmap for FDA Inspectional Oversight at https://www.fda.gov/media/148197/download.

Appendices

A. Reporting Requirements

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

Requirement	Details
Section 742(b) of the FD&C Act	"Beginning with fiscal year 2019, not later than 120 days after the end of each fiscal year during which fees are collected under this part, the Secretary shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report on the implementation of the authority for such fees during such fiscal year and the use, by the Food and Drug Administration, of the fees collected during such fiscal year for which the report is made."

B. Allowable and Excluded Costs for the AGDUFA Program

Section 741(k)(10) of the FD&C Act defines the phrase "process for the review of abbreviated applications for generic new animal drugs" to mean the following activities of FDA with respect to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions:

Included Activities	
1. The activities necessary for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions. 2. The issuance of action letters which approve abbreviated applications or supplemental abbreviated applications, or which set forth in detail the specific deficiencies in abbreviated applications, supplemental abbreviated applications, or investigational submissions and, where appropriate, the actions necessary to place such applications, supplemental applications, or submissions in condition for approval. 3. The inspection of generic new animal drug establishments and other facilities undertaken as part of the Secretary's review of pending abbreviated applications, supplemental abbreviated applications, and investigational submissions. 4. Monitoring of research conducted in connection with the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.	5. The development of regulations and policy related to the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions. 6. Development of standards for products subject to review. 7. Meetings between the Agency and generic new animal drug sponsor. 8. Review of advertising and labeling prior to approval of an abbreviated application or supplemental abbreviated application, but not after such application has been approved.

Section 741(k)(3) of the FD&C Act defines the phrase "costs of resources allocated for the process for the review of abbreviated applications for generic new animal drugs" as the expenses in connection with the process for the review of abbreviated applications for generic new animal drugs for:

Included Expenses
1. Officers and employees of FDA; contractors of FDA; advisory committees consulted with respect to the review of specific abbreviated applications, supplemental abbreviated applications, or investigational submissions, and costs related to such officers, employees, committees, and contractors, including costs for travel, education, recruitment, and other personnel activities; 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 this section and accounting for resources allocated for the review of abbreviated applications, supplemental abbreviated applications, and investigational submissions.

The AGDUFA program does not include costs related to the following activities:

Excluded Activities
1. Review of new animal drug applications and other pioneer submissions 2. Enforcement policy development 3. Post-approval surveillance and compliance activities 4. Post-approval activities relating to the review of advertising 5. Inspections unrelated to the AGDUFA program 6. Research unrelated to the AGDUFA program

C. User Fee Program History

AGDUFA was enacted in 2008 and reauthorized in 2013 (AGDUFA II) and 2018 (AGDUFA III) with the support of industry, other stakeholders, Congress, and the Administration. The FD&C Act, as amended by AGDUFA III, authorizes FDA to collect user fees from the animal drug industry to supplement the non-user fee appropriations that the Agency spends on the process for the review of abbreviated applications for generic new animal drugs. FDA spends fee revenue and non-user fee appropriations to hire, support, and maintain personnel for this review to help ensure that safe and effective generic new animal drugs reach the American public in a timely manner.

D. Conditions for Assessment and Use of Fees

Introduction

The FD&C Act, as amended by AGDUFA III, specifies three legal conditions that must be met each fiscal year for FDA to collect and spend generic new animal drug user fees. This appendix describes these legal conditions and the applicable adjustment factors, as described in the FD&C Act.

Adjustment Factor

To determine whether the legal conditions are satisfied, FDA must calculate and incorporate "adjustment factors" (as defined in section 741(k)(2)) in the assessment of the first and third legal conditions.

Section 741(k)(2) of the FD&C Act provides the following definition:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by

A. for purposes of subsection (f)(1), such Index for October 2002; and
B. for purposes of subsection (g)(2)(A)(ii), such Index for October 2007.

For the first legal condition (section 741(f)(1) of the FD&C Act) adjustment factor, the Consumer Price Index (CPI) for October 2019, the October of the fiscal year preceding FY 2021, was 257.346. The CPI for October 2002 was 181.3. Dividing the CPI of October 2019 by the CPI of October 2002 yields an adjustment factor of 1.419448 (rounded to six decimal places) for FY 2021.

For the third legal condition (section 741(g)(2)(A)(ii) of the FD&C Act) adjustment factor, the base month is October 2007. The CPI for October 2019, the October of the FY preceding FY 2021, was 257.346. The CPI for October 2007 was 208.936. Dividing the CPI of October 2019 by the CPI of October 2007 yields an adjustment factor of 1.231698 (rounded to six decimal places) for FY 2021.

Legal Conditions

First legal condition: FDA's Salaries and Expenses appropriation (excluding user fees) for FY 2003 was $1,373,714,000. Multiplying this amount by the adjustment factor of 1.419448 (rounded to the sixth decimal place) equals $1,949,915,590.

Second legal condition: Division A, Title VI of Public Law 116-260 specified that $22,797,000 shall be derived from generic new animal drug user fees, and that generic new animal drug user fees collected in excess of this amount, if any, are appropriated for FDA.

Third legal condition: In FY 2008, the amount spent from appropriations for the AGDUFA program was $5,510,000 (rounded to the nearest thousand). After applying the adjustment factor of 1.231698 (rounded to the sixth decimal place), the minimum appropriation spending level for the AGDUFA program for FY 2021, excluding user fees, is $6,786,656.

Exhibit 7 below provides the details regarding each of the three legal conditions that must be met each fiscal year, as quoted from the FD&C Act.

Exhibit 7: Legal Conditions

Legal Condition #	FD&C Act Section	Details
1	741(f)(1)	Fees may not be assessed under [section 741(a) of the FD&C Act] for a fiscal year beginning after fiscal year 2008 unless appropriations for salaries and expenses of the Food and Drug Administration for such fiscal year (excluding the amount of fees appropriated for such fiscal year) are equal to or greater than the amount of appropriations for the salaries and expenses of the Food and Drug Administration for the fiscal year 2003 (excluding the amount of fees appropriated for such fiscal year) multiplied by the adjustment factor applicable to the fiscal year involved.
2	741(g)(2)(A)(i)	The fees authorized by [section 741 of the FD&C Act]--subject to [section 741(g)(2)(C)], shall be collected and available in each fiscal year in an amount not to exceed the amount specified in appropriation Acts, or otherwise made available for obligation for such fiscal year.
3	741(g)(2)(A)(ii)	The fees authorized by [section 741 of the FD&C Act] shall be available to defray increases in the costs of the resources allocated for the process for the review of abbreviated applications for generic new animal drugs (including increases in such costs for an additional number of full-time equivalent positions in the Department of Health and Human Services to be engaged in such process) over such costs, excluding costs paid from fees collected under this section, for fiscal year 2008 multiplied by the adjustment factor.

E. Financial Notes

Note 1. 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 2. Payroll and Operating Costs

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

For payroll, employees are required to report their time in an activity-based reporting system, which allows FDA to identify activities that user fees can be used to support. See **Appendix B** for a listing of those activities. For operating activities (e.g., contracting services), funds are allocated based on the proportion to which those activities support the AGDUFA program. If an operating activity solely supports AGDUFA, it will be fully funded by the program. If the operating activity is shared, AGDUFA will fund the activity in proportion to its level of use by the program as compared to other programs.

Note 3. Rent Costs

GSA charges rent to FDA for the federal buildings that FDA occupies. Rental rates vary based on the type and location of the space provided. Because rent is an essential support cost for the process for the review of abbreviated applications for generic new animal drugs, a portion of those charges is paid from non-user fee appropriations and a portion is paid from AGDUFA fees. Also included in this account are recurring costs that FDA pays to non-federal sources under the delegation of direct lease and service authority. These services include rental of space and all recurring services for building operations such as 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 4. Shared Services Costs

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

- **FDA Central**: Provides for Center-wide and Agency-wide services such as telecommunications, training, printing, mail and document management, IT systems, employee health units, and other support and miscellaneous services.
- **Employee Resource & Information Center**: 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 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 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, including providing workforce training, maintaining employee relations, and promoting collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust, and mutual respect.
- **Office of Talent Solutions:** To provide high quality and efficient human resources solutions that enable FDA to hire a talented and qualified workforce.

Note 5. Inflation Adjustment

The fee revenue amount established in AGDUFA III for FY 2020 and subsequent fiscal years is subject to adjustment to account for inflation. The inflation adjustment adjusts the annual fee revenue amounts specified in the AGDUFA statute (see section 741(b)(1) of the FD&C Act) to maintain the purchasing power of fee funds despite inflation. The adjustment adjusts the non-payroll-related portion by changes in the CPI and adjusts the payroll-related portion by changes in FDA's average personnel compensation and benefits.

In August 2020, FDA set fees for FY 2021 in accordance with the amounts specified in AGDUFA III (see 85 FR 46647, August 3, 2020). The fee revenue amount is adjusted each year after FY 2019 to reflect changes in inflation and review workload, if applicable. For FY 2021, the fee revenue amount was adjusted by 1.2850 percent to account for inflation.

Note 6. Workload Adjustment

The fee revenue amounts established in AGDUFA III for FY 2020 and subsequent fiscal years are also subject to adjustment to reflect changes in FDA's workload for the process for the review of abbreviated

applications. A workload adjustment will be applied to the inflation-adjusted fee revenue amount (section 741(c)(3) of the FD&C Act).

To apply the workload adjustment, AGDUFA III specifies that FDA shall calculate the weighted average of the change in the total number of each of the four types of applications and submissions specified in the workload adjustment provision: 1) abbreviated applications for generic new animal drugs, 2) manufacturing supplemental abbreviated applications for generic new animal drugs, 3) investigational generic new animal drug study submissions, and 4) investigational generic new animal drug protocol submissions.

In August 2020, FDA set fees for FY 2021 in accordance with the amounts specified in AGDUFA III (see 85 FR 46647, August 3, 2020). The fee revenue amount is adjusted each year after FY 2019 to reflect changes in review workload, if applicable. For FY 2021, the fee revenue amount was adjusted (increased) by 28.3333 percent to account for increased workload.

Under section 741(c)(3)(B) of the FD&C Act, for FYs 2021 through 2023, if application of the workload adjustment increases the amount of fee revenue established for the fiscal year, as adjusted for inflation, the fee revenue increase will be reduced by the amount of any excess collections for the second preceding fiscal year, up to the amount of the fee revenue increase for workload.

Note 7. Future Year Refunds Allowance, Set Aside

If a sponsor pays the fee for an abbreviated application which is subsequently refused for filing, the sponsor receives a refund for 75 percent of the fee paid (section 741(a)(1)(D) of the FD&C Act). If an abbreviated application is withdrawn after the application has been filed, the sponsor may receive a refund of the fee or portion of the fee paid if no substantial work was performed by the Agency on the application after it was filed (section 741(a)(1)(E) of the FD&C Act).

To qualify for consideration for a waiver or reduction in fees, or for a refund, a written request must be submitted to FDA no later than 180 days after such fee is due (section 741(i) of the FD&C Act).

Note 8. Minimum Non-User Fee Appropriations Adjustment Factor

FDA must calculate and incorporate an adjustment factor for the third legal condition. For purposes of AGDUFA III, the following definition is applied:

> The term "adjustment factor" applicable to a fiscal year is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by[,] … for purposes of [section 741(g)(2)(A)(ii) of the Act (the third legal condition)], such Index for October 2007 (section 741(k)(2)(B) of the FD&C Act).