

# **FIVE-YEAR FINANCIAL PLAN**

**Fiscal Years**

**2018-2019-2020-2021-2022**

**2022 Update**

**FOR THE**

## **GENERIC DRUG USER FEE AMENDMENTS**

### **PROGRAM**

**FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES**



**U.S. FOOD & DRUG  
ADMINISTRATION**

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## ***Five-Year Plan Overview***

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### **A. Scope**

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

### **B. Five-Year Plan Commitments**

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

### **C. Updates to the Five-Year Plan**

All estimates in the plan are subject to review and reassessment each fiscal year as the actual amounts for appropriations, obligations, and collections for the previous year become available. The five-year financial plan provides the baseline from which future changes will be made. Updates to the five-year financial plan will occur on an annual basis and cover the 5 years in the current reauthorization period.

## ***Management Discussion***

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### **D. Organization Background**

FDA is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. FDA also has responsibility for regulating the manufacturing, marketing, and distribution of tobacco products and advancing the public's health by helping to speed innovations that make medical products more effective, safer, and more affordable and by helping the public get accurate, science-based information needed to use medical products and consume foods to maintain and improve their health. FDA similarly plays a significant role in the nation's counterterrorism capability.

#### **Program Organization**

There are four major FDA components that support the GDUFA program: the Center for Drug Evaluation and Research (CDER), the Center for Biologics Evaluation and Research (CBER), the Office of Regulatory Affairs (ORA), and Headquarters (HQ).

**Exhibit 1** provides an overview of the mission for each of these components.

## Exhibit 1: User Fee Program Components

| Component | Mission  |
|-----------|--|
| CDER      | Protects and promotes public health by helping to ensure that human drugs are safe and effective, meet established quality standards, and are available to patients. |
| CBER      | Protects and advances the public health by helping to ensure that biological products are safe and effective, and are available to patients.                         |
| ORA       | Protects consumers and enhances public health by maximizing compliance of FDA regulated products and minimizing risk associated with those products.                 |
| HQ        | Provides FDA-wide program direction and administrative services to ensure FDA's consumer and patient safety programs are effectively and efficiently managed.        |

### User Fee Governance

The Agency's expanding level of user fees, the reporting of agency performance commitments associated with these fees, and the need for FDA to convey how these fees are executed calls for strong financial governance. This includes an understanding of the design of these programs, clear financial plans, data-driven decisions on resource allocation, consistency and transparency about assumptions, reliable financial forecasting, and accountability for resources spent.

FDA's user fee governance process leverages the User Fee Financial Management Committee (UFFMC), which consists of senior financial, business operations, and program experts across the agency who 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.

## E. User Fee Background and Structure

The GDUFA provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) authorize FDA to assess and collect fees from industry to supplement non-user fee appropriations that the Agency spends on human generic drug activities.

The FDA Reauthorization Act of 2017 (FDARA) included the reauthorization of GDUFA, known as GDUFA II, for the period from October 1, 2017, through September 30, 2022. This five-year reauthorization ensures continued funding for FDA from FY 2018 through FY 2022 to support program innovation, evaluation, and improvement. GDUFA II user fees fund critical and measurable enhancements to the performance of FDA's generic drugs program, bringing greater predictability and timeliness to the review of generic drug applications. FDA spends appropriated GDUFA user fee collections and non-user fee appropriations to hire, support, and maintain personnel for human generic drug activities to help ensure that safe, effective, and high-quality generic drug products are available to the American public.

Under GDUFA II, some key changes were made to the GDUFA fee structure:

1. There is no longer a filing fee for a prior approval supplement (PAS)..
2. No facility or abbreviated new drug application (ANDA) applicant will be charged an annual facility fee until an ANDA is approved.

3. Contract Manufacturing Organizations (CMO) will pay one-third the annual fee paid by firms that manufacture under ANDAs which they or their affiliates own.
4. A person and affiliates will pay one program fee commensurate with the number of approved ANDAs that the firm and its affiliates collectively own.

Exhibit 2 outlines the GDUFA II user fee structure.

### Exhibit 2: GDUFA II Fee Structure

| Fee Type                                       |   | Definition   |
|--|---|--|
| <b>Abbreviated New Drug Application (ANDA)</b> |   | An ANDA filing fee is incurred upon submission of an abbreviated new drug application.   |
| <b>Program</b>                                 | <i>Small</i>  | Each person and affiliates will be assessed an annual fee depending on the number of approved ANDAs in the person's portfolio.   |
|  | <i>Medium</i>   |  |
|  | <i>Large</i>  |  |
| <b>Facility</b>                                | <i>Domestic Active Pharmaceutical Ingredients (API)</i>   | An API facility fee is owed by each person who owns a facility that is identified in (1) at least one approved generic drug submission in which the facility is approved to produce one or more APIs or (2) a Type II API drug master file referenced in at least one approved generic drug submission. An additional \$15,000 is assessed for a facility located outside the United States and its territories and possessions. |
|  | <i>Foreign API</i>  |  |
|  | <i>Domestic Finished Dosage Form (FDF)</i>                | An FDF facility fee is owed by each person who owns a facility that is identified in at least one generic drug submission that is approved to produce one or more finished dosage forms of a human generic drug. An additional \$15,000 is assessed for a facility located outside the United States and its territories and possessions.  |
|  | <i>Foreign FDF</i>  |  |
|  | <i>Domestic Contract Manufacturing Organization (CMO)</i> | An annual CMO facility fee is owed by each person who owns an FDF facility that is identified in at least one approved ANDA, where the facility is not identified in an approved ANDA held by the owner of that facility or its affiliates. An additional \$15,000 is assessed for a facility located outside the United States and its territories and possessions.   |
|  | <i>Foreign CMO</i>  |  |
| <b>Type II, API Drug Master File (DMF)</b>     |   | The one-time DMF fee is incurred on whichever of the following dates occurs earlier: (1) the first time a generic drug submission references that DMF by an initial letter of authorization on or after October 1, 2012, or (2) the date the DMF holder requests the initial completeness assessment.  |

The statute specifies how the fees must be calculated each fiscal year, including annual adjustments that must be made for inflation. The fee amounts are to be published in the Federal Register each year; this typically occurs at the beginning of August ([GDUFA User Fee Rates](#)), for the fiscal year beginning October 1.

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

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

## F. Forward View

The current authorization for the GDUFA program will expire at the conclusion of FY 2022 (September 30, 2022). The future of the program is dependent on timely reauthorization. The Agency has developed

a package of recommendations developed through a process required in statute<sup>1</sup> and the Secretary has transmitted these recommendations to the Congressional authorizing Committees. Information on this reauthorization process is available at <https://www.fda.gov/industry/generic-drug-user-fee-amendments/gdufa-iii>.

As the current program is set to expire and is pending reauthorization at the time of publication of this plan, FDA cannot currently project the financial position of the program after FY 2022.

FDA does expect that many of the recent external factors impacting the program are likely to continue to impact the program in the coming years. This includes continued high-levels of workload resulting from industry submissions, potential impact due to COVID-19 pandemic, and continued competition for the necessary scientific and technical talent needed to deliver GDUFA performance commitments and related public health priorities.

### **Discussion of Workload and Other Activities in GDUFA**

GDUFA is a maturing program, now at the end of its second authorization period. It faces a high workload and unique programmatic and regulatory complexities as it continues to mature. The review timeframes in GDUFA II are much more aggressive than in GDUFA I. In addition, FDA has received an unanticipated significant increase in workload particularly with post approval change submissions (i.e., prior approval supplements (PASs)) and Controlled Correspondence (CC) submissions. During FY 2021, FDA received 3,897 CCs, a number that has more than quadrupled since the beginning of GDUFA and 1,351 PASs, a number that has more than tripled since the beginning of GDUFA. The generic drug program's efficiency, quality, and predictability have evolved and matured due largely to the resources provided through user fees. While the Agency has continued to meet a majority of its GDUFA commitments, the unexpected increase in workload is putting considerable strain on the program.

Additionally, some unforeseen trends in the generic drug industry and the COVID-19 pandemic have added more workload. A great deal of manufacturing has moved overseas which has resulted in the need for FDA to conduct more foreign inspections which tend to be more expensive. That expense is largely offset by the foreign fee differential that overseas manufacturing facilities pay. However, other unpredictable trends in the market could likewise impact FDA's resource consumption. The unprecedented COVID-19 public health emergency demanded the generic drug program pivot to prioritizing the assessment of generic drug submissions involving potential treatments and supportive therapies for patients with COVID-19. The program worked diligently to support manufacturers of approved generic drugs who needed to make changes to manufacturing processes or facilities to address disruptions caused by the pandemic; including antibiotics, sedatives used in ventilated patients, anticoagulants, and pulmonary medications, among others.

A new program for complex generic drugs<sup>2</sup> was established under GDUFA II, in which FDA provides additional support to applicants in preparing an approvable ANDA. This support helps applicants prepare more complete submissions, which promotes a more efficient and effective ANDA review process to reduce the number of review cycles required to obtain an ANDA approval. CDER's Office of Pharmaceutical Quality (OPQ) conducts research and testing on complex generic drugs to develop a lifecycle research paradigm to proactively identify scientific and technical review challenges posed by

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<sup>1</sup> Section 744C(f) of the FD&C Act.

<sup>2</sup> Complex generic drugs are those generics for "complex products" as defined in the GDUFA II commitment letter <https://www.fda.gov/media/101052/download>

complex drug products. This helps reviewers evaluate these ANDAs more efficiently by establishing clear standards and methods, improving OPQ's readiness to evaluate applications.

There are also other technology enhancements in development such as OPQ's Knowledge-Aided Assessment & Structured Application (KASA) platform which will enhance lifecycle management of drug products. GDUFA is the first program for which KASA is being developed.

FDA is focused on building staff capacity to manage the increasing program workload, meet performance goals, and deliver on commitments funded in GDUFA II. An essential part of the GDUFA II Commitment Letter is FDA's agreement to develop a resource management planning function (resource capacity planning function) and modernized time reporting approach in GDUFA II. These commitments, agreed upon by the generic drug industry and FDA, recognize the importance of providing the Agency with a firm financial path to meet all of its commitments when there are fluctuations in workload. In addition, FDA committed to obtaining through a contract with an independent third party an evaluation of options and recommendations on a new methodology to accurately assess changes in the resource needs of the human generic drug review program and how to monitor and report on those needs moving forward. On August 3, 2020, FDA announced the publication of a report<sup>3</sup>, entitled "Independent Evaluation of the GDUFA Resource Capacity Planning Adjustment Methodology"<sup>4</sup>, which reflects Booz Allen Hamilton's independent assessment of FDA's proposed capacity planning adjustment (CPA) methodology for the GDUFA program. FDA continues to assess the recommendations by Booz Allen Hamilton regarding potential enhancements to the CPA which —if the CPA is implemented as anticipated through GDUFA's pending reauthorization— could provide a path forward to ensure the Agency can sustain the program through unexpected fluctuations in direct review work.

### **Efforts to Enhance Financial Management**

GDUFA I was a \$1.5 billion agreement covering 5 years. During the first 2 years of GDUFA I, as the program was being built, FDA spent significantly less than it collected due to a 2 – 3 year lag in meeting staffing needs. Therefore, the carryover balance grew quickly. Eventually, as the program matured, FDA's spending levels increased to exceed its annual collections amounts. Part of the increased spending was due to bringing on term-employees to manage the high pending workload. FDA entered GDUFA II with a carryover balance from GDUFA I, but expected obligations and collections to even out over the course of GDUFA II.

At the end of FY 2021, the carryover balance was \$127,223,404 which would provide for approximately 12 weeks of operations. FDA considers a carryover level between 8 – 12 weeks as a reasonable amount of carryover to maintain for the GDUFA program. This level of carryover would provide FDA with sufficient reserves to mitigate possible financial risks to the program, such as under collections or a lapse in appropriations.

FDA continues to strive to hire scientific and regulatory staff, while also making targeted strategic investments to enhance productivity, support regulatory science and policy efforts, and ensure the availability of safe and effective generic drug products. FDA will continue working to ensure the financial resources available to the GDUFA program are being utilized to support the long-term sustainability and productivity of the review program.

FDA also made commitments in GDUFA II to enhance efficiency and transparency in the administration of GDUFA's financial resources. This included a third-party evaluation of GDUFA program resource

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<sup>3</sup> <https://www.federalregister.gov/documents/2020/08/03/2020-16794/assessing-the-resource-needs-of-the-generic-drug-user-fee-amendments-publication-of-report-request>

<sup>4</sup> <https://www.fda.gov/media/140656/download>

management in FY 2018.<sup>5</sup> It also included the publishing of a five-year plan (this plan), to be updated annually. FDA also held annual public meetings (starting in FY 2019) which discussed this five-year financial plan, along with the Agency’s progress in implementing resource capacity planning, modernized time reporting, and the impact of the user fee structure changes under GDUFA II.<sup>6</sup>

### **Working Capital Fund/Cost Allocation**

FDA has a Cost Allocation and Recovery framework to improve financial management of user fee resources under the FD&C Act's GDUFA, the Prescription Drug User Fee Act (PDUFA) and the Biosimilar User Fee Act (BsUFA) programs. Congress authorized FDA to establish a Working Capital Fund (WCF) to finance centralized services (see section 722 of Division A of P.L. 115-141). The WCF benefits the financial management of Agency funds by:

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

## ***Financial Information***

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This section provides an overview of the financial outlook for GDUFA through the FY 2018 – FY 2022 reauthorization period including user fee revenue, obligations, carryover, non-user fee appropriations requirements, and planned hiring. Refer to prior year GDUFA Five-Year Financial Plans for additional information on prior year estimates.<sup>7</sup>

### **G. User Fee Program Financials**

**Table 1** represents a summary of the forecasted GDUFA financial position, as it relates to user fee resources (collections and carryover). This table also provides an overview of planned obligations for which the user fee resources would be used. The financial notes can be found in **Appendix C**.

**Table 1: Human Generic Drug Collections, Obligations, and Carryover for Fiscal Year 2018 through Fiscal Year 2022<sup>8</sup>**

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<sup>5</sup> <https://www.fda.gov/drugs/development-resources/fiscal-year-2018-financial-management-evaluation-human-drug-user-fees-assessment-report>

<sup>6</sup> <https://www.fda.gov/drugs/news-events-human-drugs/financial-transparency-and-efficiency-prescription-drug-user-fee-act-biosimilar-user-fee-act-and>

<sup>7</sup> <https://www.fda.gov/about-fda/user-fee-reports/user-fee-five-year-financial-plans>

<sup>8</sup> The values in this table provide a year-to-year evaluation. Values are updated on a yearly basis. In the first year of the authorization period, estimates for all five years are included. In subsequent years of the authorization, the actual values replace the estimated values; the previous year’s estimates are kept to compare with the actual values. The actual values are based on year-end reporting; thus, mid-year reporting in the current year does not occur in this report.



| Budgetary Resources                | Notes         | FY18                 | FY19                 | FY20                 | FY21                 | FY21                 | FY22                 |
|------------------------------------|---------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
|                                    |               | Actual               | Actual               | Actual               | Estimate             | Actual               | Estimate             |
| <b>Target Revenue</b>              | <b>Note 1</b> | \$493,600,000        | \$501,721,000        | \$513,223,000        | \$520,209,000        | \$520,209,000        | \$539,656,000        |
| Cash Collections                   |               | \$493,655,974        | \$496,503,494        | \$483,285,782        | \$520,209,000        | \$500,205,882        | \$539,656,000        |
| Recoveries                         | Note 2        | \$4,920,184          | \$8,544,957          | \$9,968,653          | \$7,000,000          | \$6,535,880          | \$7,000,000          |
| Total Carryover, Beginning of Year |               | \$142,412,048        | \$163,715,667        | \$204,171,168        | \$156,731,582        | \$156,731,582        | \$127,223,404        |
| <b>Total Budgetary Resources</b>   |               | <b>\$640,988,205</b> | <b>\$668,764,117</b> | <b>\$697,425,603</b> | <b>\$683,940,582</b> | <b>\$663,473,344</b> | <b>\$673,879,404</b> |

| Obligations               | Notes  | FY18                 | FY19                 | FY20                 | FY21                 | FY21                 | FY22                 |
|---------------------------|--------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
|                           |        | Actual               | Actual               | Actual               | Estimate             | Actual               | Estimate             |
| Total Payroll & Operating | Note 3 | \$397,961,320        | \$384,721,323        | \$461,787,043        | \$473,800,227        | \$455,785,469        | \$486,252,904        |
| Total Rent                | Note 4 | \$22,019,962         | \$24,962,969         | \$19,802,082         | \$26,313,583         | \$23,037,004         | \$26,576,719         |
| Total Shared Services     | Note 5 | \$57,291,257         | \$54,908,657         | \$59,104,896         | \$60,980,714         | \$57,427,467         | \$64,738,821         |
| <b>Total Obligations</b>  |        | <b>\$477,272,539</b> | <b>\$464,592,949</b> | <b>\$540,694,021</b> | <b>\$561,094,525</b> | <b>\$536,249,940</b> | <b>\$577,568,444</b> |

| Carryover                                      | Notes | FY18                 | FY19                 | FY20                 | FY21                 | FY21                 | FY22                |
|--|-------|----------------------|----------------------|----------------------|----------------------|----------------------|---------------------|
|  |       | Actual               | Actual               | Actual               | Estimate             | Actual               | Estimate            |
| Total Carryover, End of Year                   |       | \$163,715,667        | \$204,171,168        | \$156,731,582        | \$122,846,058        | \$127,223,404        | \$96,310,960        |
| Future Year Refunds Allowance, Set Aside       |       | (\$5,000,000)        | (\$5,000,000)        | (\$4,000,000)        | (\$4,000,000)        | (\$4,000,000)        | (\$4,000,000)       |
| <b>Carryover Net of Set Aside, End of Year</b> |       | <b>\$158,715,667</b> | <b>\$199,171,168</b> | <b>\$152,731,582</b> | <b>\$118,846,058</b> | <b>\$123,223,404</b> | <b>\$92,310,960</b> |

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 annual revenue amount established when fees for the fiscal year are set. Cash collections are the actual amount collected during the fiscal year and are forecasted to be equal to the target revenue. GDUFA II specifies how the fees must be calculated each fiscal year, including annual adjustment that must be made for inflation and (as applicable) the final year adjustment.

For the purposes of this plan, future year recoveries are estimated to be \$7 million annually. Additional details on recoveries are included in **Note 2**.

**Obligations:** The obligations component of **Table 1** shows the FY 2018 through FY 2021 actual expenditure and planned annual expenditure for FY 2022 of GDUFA fee funds broken out into major expense categories. GDUFA fees may be expended only for costs to support "human generic drug activities," as defined in GDUFA II.

**Carryover:** GDUFA fees collected, appropriated, and not obligated at the end of the fiscal year remain available to support the GDUFA program in future fiscal years. In this report, such fee funds are referred to as the "total carryover" or "GDUFA carryover". Maintaining an appropriate level of carryover enables FDA to mitigate financial risks to the program, including, for example, the risk of under collecting fees

and the risk of a lapse in appropriations, so FDA can continue performing human generic drug activities under financial constraints. The unobligated GDUFA funds at the end of each fiscal year are referred to as the “carryover” of **Table 1**.

## H. User Fee Revenue

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

FDA assumes, for planning purposes, that cash collections will equal the target revenue amount. Cash collections may differ from the annual target revenue amount if the actual number of fee-paying units differ from the number of fee-paying units estimated when fees are set each year.

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

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

| Budgetary Resources         | Notes | FY18                 | FY19                 | FY20                 | FY21                 | FY22                 |
|-----------------------------|-------|----------------------|----------------------|----------------------|----------------------|----------------------|
|                             |       | Actual               | Actual               | Actual               | Actual               | Actual               |
| Statutory Base              |       | \$493,600,000        | \$493,600,000        | \$501,721,201        | \$513,223,160        | \$520,208,640        |
| Inflation Adjustment        |       | \$0                  | \$8,121,201          | \$11,501,959         | \$6,985,480          | \$11,158,996         |
| Final Year Adjustment       |       | N/A                  | N/A                  | N/A                  | N/A                  | \$8,288,102          |
| <b>Target Revenue Total</b> |       | <b>\$493,600,000</b> | <b>\$501,721,000</b> | <b>\$513,223,000</b> | <b>\$520,209,000</b> | <b>\$539,656,000</b> |

| Budgetary Resources                |  | FY18                 | FY19                 | FY20                 | FY21                 | FY21                 | FY22                 |
|------------------------------------|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
|                                    |  | Actual               | Actual               | Actual               | Estimate             | Actual               | Estimate             |
| Cash Collections                   |  | \$493,655,974        | \$496,503,494        | \$483,285,782        | \$520,209,000        | \$500,205,882        | \$539,656,000        |
| Recoveries                         |  | \$4,920,184          | \$8,544,957          | \$9,968,653          | \$7,000,000          | \$6,535,880          | \$7,000,000          |
| Total Carryover, Beginning of Year |  | \$142,412,048        | \$163,715,667        | \$204,171,168        | \$156,731,582        | \$156,731,582        | \$127,223,404        |
| <b>Total Budgetary Resources</b>   |  | <b>\$640,988,205</b> | <b>\$668,764,117</b> | <b>\$697,425,603</b> | <b>\$683,940,582</b> | <b>\$663,473,344</b> | <b>\$673,879,404</b> |

Target Revenue has been rounded to the nearest thousand dollars

Numbers have been rounded to the nearest dollar

†Indicates an actual amount

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

The process for setting the annual target revenue is defined in statute. Each year’s base revenue is adjusted for inflation. In addition, FDA may further increase the fee revenue and fees in the final year of the authorization (FY 2022) through a final year adjustment as described below:

- **Inflation Adjustment:** The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation. The adjustment is a composite measure that weights operating expenses by changes in the applicable Consumer Price Index

(CPI)<sup>9</sup> and payroll-related expenses by changes in FDA’s average personnel compensation and benefits amounts.

There was no inflation adjustment in FY 2018; the actual inflation adjustment utilized in FY 2019, FY 2020, FY2021 and FY 2022 was 1.6453, 2.2925, 1.3611, and 2.1451 percent (rounded) respectively.

- **Final Year Adjustment:** For FY 2022, FDA may, in addition to the inflation adjustment, further increase the fee revenue and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2023. The legislative language authorizing the final year adjustment allows FDA discretion in whether to make this adjustment for a full 3 months of operating reserves or a shorter period. FDA decided to make the final adjustment to allow for only 7 weeks of operating reserves resulting in a final year adjustment of \$8,288,102. The rationale for the amount of the increase was contained in the annual notice establishing fee revenues and fees for FY 2022<sup>10</sup>.

Unlike PDUFA or BsUFA, GDUFA does not currently provide for a capacity planning adjustment to adjust the annual target revenue based on changes in workload. Accordingly, unanticipated increases in submissions will lead to a situation in which FDA will be expected to maintain the same level of performance at the higher workload level without a commensurate increase in fee revenues to fund the additional needed staffing.

Fee rates are established each year so that revenues from ANDA fees provide 33 percent of the total revenue, DMF fees provide 5 percent of the total revenue, FDF and CMO facility fees provide 20 percent of the total revenue, API facility fees provide 7 percent of the total revenue, and GDUFA program fees provide 35 percent of the total revenue. 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.

Collections in FY 2021 were about \$20 million, or about 4 percent, below the target revenue amount. This may be, in part, a result of the COVID-19 pandemic on the industry leading to fewer fee-paying submissions during the fiscal year.

**Table 3** presents the forecasted and actual total annual collections by fee type and cohort year.

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<sup>9</sup> The “Washington-Baltimore, DC-MD-VA-WV” CPI specified in the statute was discontinued by the Bureau of Labor Statistics and the agency is using the new “Washington-Arlington-Alexandria, DC-MD-VA-WV” CPI. <https://www.bls.gov/cpi/additional-resources/geographic-revision-2018.htm>

<sup>10</sup> [Federal Register :: Generic Drug User Fee Rates for Fiscal Year 2022](#)

**Table 3: GDUFA II Collections**

| Fee Type                            | Cohort Year | 2018                 | 2019                 | 2020                 | 2021                 | 2021                 | 2022                 |
|-------------------------------------|-------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
|                                     | Cost Type   | Actual               | Actual               | Actual               | Estimate             | Actual               | Estimate             |
| ANDA (Application) Fees             |             | \$168,644,366        | \$157,051,641        | \$144,169,904        | \$171,668,970        | \$151,955,931        | \$178,086,480        |
| DMF Fees                            |             | \$22,718,775         | \$23,820,629         | \$21,210,765         | \$26,010,450         | \$27,758,637         | \$26,982,800         |
| Facilities Fees (FDF, CMO, and API) |             | \$147,283,511        | \$149,103,078        | \$143,820,799        | \$140,456,430        | \$139,908,244        | \$145,707,120        |
| GDUFA Program Fees                  |             | \$144,443,886        | \$178,581,880        | \$173,645,928        | \$182,073,150        | \$179,755,612        | \$188,879,600        |
| <b>Total Cash Collections</b>       |             | <b>\$483,090,538</b> | <b>\$508,557,228</b> | <b>\$482,847,396</b> | <b>\$520,209,000</b> | <b>\$499,378,424</b> | <b>\$539,656,000</b> |

Estimated Total Cash Collections have been rounded to the nearest thousand dollars  
 All other numbers have been rounded to the nearest dollar

## I. User Fee Obligations

**Table 4** provides a breakout of planned user fee obligations by expense category for the 5 years represented in this plan. This plan provides actual amounts for the preceding fiscal years, as well as updated planned amounts for the remaining fiscal year. The financial notes can be found in **Appendix C**.

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

| User Fee Obligations           | Notes  | FY18                  | FY19                  | FY20                  | FY21                  | FY21                  | FY22                  |
|--------------------------------|--------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|-----------------------|
|                                |        | Actual                | Actual                | Actual                | Estimate              | Actual                | Estimate              |
| <b>Payroll &amp; Operating</b> | Note 3 |                       |                       |                       |                       |                       |                       |
| CBER                           |        | \$49,462              | \$23,658              | \$131,615             | \$1,018,541           | \$118,344             | \$1,040,390           |
| CDER                           |        | \$323,591,582         | \$316,437,772         | \$378,276,891         | \$385,402,867         | \$384,542,262         | \$399,022,266         |
| ORA                            |        | \$46,518,651          | \$40,694,363          | \$48,355,675          | \$49,604,248          | \$41,354,289          | \$51,129,752          |
| HQ                             |        | \$27,801,624          | \$27,565,531          | \$35,022,863          | \$37,774,571          | \$29,770,574          | \$35,060,496          |
| Total Rent                     | Note 4 | \$22,019,962          | \$24,962,969          | \$19,802,082          | \$26,313,583          | \$23,037,004          | \$26,576,719          |
| Total Shared Services          | Note 5 | \$57,291,257          | \$54,908,657          | \$59,104,896          | \$60,980,714          | \$57,427,467          | \$64,738,821          |
| <b>Total Obligations</b>       |        | <b>\$ 477,272,539</b> | <b>\$ 464,592,949</b> | <b>\$ 540,694,021</b> | <b>\$ 561,094,525</b> | <b>\$ 536,249,940</b> | <b>\$ 577,568,444</b> |

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 GDUFA fees may be expended, as set forth in statute. This includes, for example, core regulatory review functions, pre-approval inspections, guidance and policy development activities, certain scientific and research activities, and management and administrative functions that support the GDUFA program. **Appendix A** provides additional information regarding allowable and excluded costs for the GDUFA program.
- **Rent:** This 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 (see Note 4). Rent is charged at different rates depending on the type and location of the space provided.

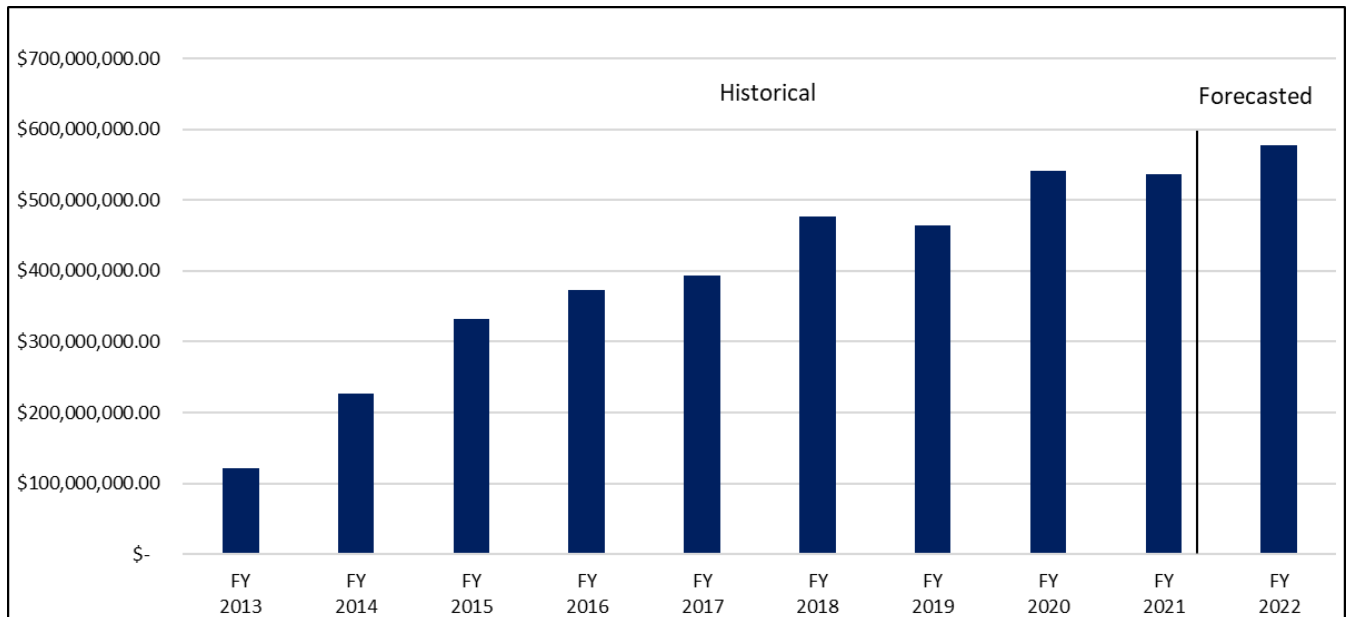
- **Shared Services:** FDA has several shared service organizations that provide support across the user fee programs, such as human resources and IT. Shared services at FDA are located within the WCF. Yearly costs are determined by the Cost Allocation and Recovery framework discussed previously. In FY 2021, the WCF absorbed several offices that were previously located within HQ. This change is responsible for the variance in HQ and Shared Services from the original plan, published in FY 2018, for FY 2021 and beyond. **Note 5** provides a full list of what is contained in the WCF.

Variations occurred between the original FY -20212021 plan and the actuals in some areas:

- **CBER Obligations:** Actual CBER obligations in FY 2021 were lower than estimated due to a lower amount of workload than anticipated. GDUFA funding will not be utilized unless the GDUFA-related workload at CBER requires it.
- **HQ Obligations:** Actual HQ obligations were lower in FY 2021 due to transfers into the WCF as well as returns from specific offices that were unable to hire. These offices will continue to make efforts to bring new hires on board.
- **ORA Obligations:** Actual ORA obligations in GDUFA were lower than anticipated due to the Agency reducing foreign travel out of safety concerns for employees related to the pandemic. This led to lower than planned spending on foreign inspectional travel. ORA has also experienced some delays in funding IT requisitions.
- **Rent:** The variances in rent actuals for FY 2021 were due to a lower rent bill than anticipated. While small fluctuations are common, FDA does not anticipate large variances in the Rent account in future fiscal years.
- **Shared Services:** Shared Services obligations were adjusted to reflect a redistribution of costs by funding source, which caused an overall decrease of GDUFA user fee obligations in Shared Services in FY 2021.

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

**Exhibit 3: Historical and Forecasted User Fee Obligations by Fiscal Year**



As demonstrated by this graph, there has been a relatively steady increase in program expenditures in the past 5 years. FY 2021 spending was at a slightly reduced level than that of FY 2020.

## J. User Fee Carryover

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

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. For the GDUFA program, FDA considers an amount equivalent to between 8 – 12 weeks of operations (\$83 million – \$124 million in FY 2022) to be a reasonable range to mitigate these risks.

The net change in carryover balance each year is equal to cash collections minus net obligations. This is shown in **Table 1** above.

**Table 5** provides projections of GDUFA carryover balances at the end of each fiscal year. The financial notes can be found in **Appendix C**.

**Table 5: GDUFA Carryover by Fiscal Year**

| Carryover                                      | Notes | FY18          | FY19          | FY20          | FY21          | FY21          | FY22          |
|--|-------|---------------|---------------|---------------|---------------|---------------|---------------|
|  |       | Actual        | Actual        | Actual        | Estimate      | Actual        | Estimate      |
| <b>Total Carryover, End of Year</b>            |       | \$163,715,667 | \$204,171,168 | \$156,731,582 | \$122,846,058 | \$127,223,404 | \$96,310,960  |
| Future Year Refunds Allowance, Set Aside       |       | (\$5,000,000) | (\$5,000,000) | (\$4,000,000) | (\$4,000,000) | (\$4,000,000) | (\$4,000,000) |
| <b>Carryover Net of Set Aside, End of Year</b> |       | \$158,715,667 | \$199,171,168 | \$152,731,582 | \$118,846,058 | \$123,223,404 | \$92,310,960  |

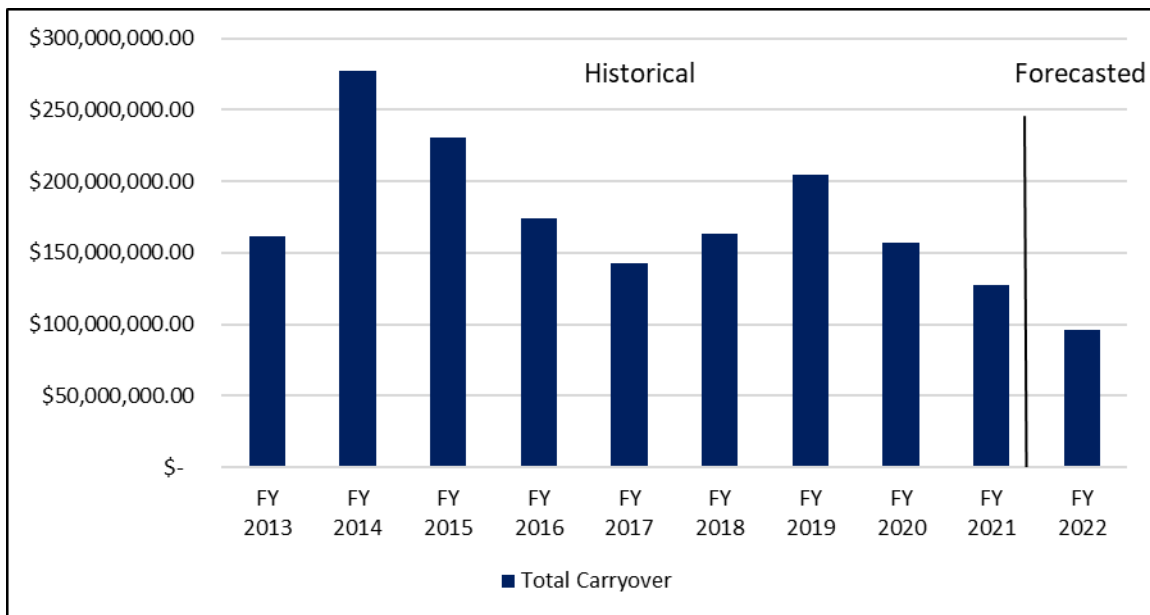
Numbers have been rounded to the nearest dollar

These terms are defined below:

- **Total Carryover, End of Year** – This is the total amount of unobligated funds at the end of the fiscal year.
- **Future Year Refunds Allowance, Set Aside** – FDA maintains a small amount to provide for future year refunds, as a matter of prudent operations. For that purpose, a total of \$4,000,000 in fee funds available for obligation is being set aside. See **Note 6** for additional details.
- **Carryover Net of Set Aside, End of Year** – This is the total carryover less any carryover funds subject to set asides.

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

**Exhibit 4: Historical and Forecasted Carryover by Fiscal Year**



The operations in FY 2021 resulted in a net decrease of the carryover of \$29,508,178, from \$156,731,582 at the end of FY 2020 to \$127,223,404 at the end of FY 2021. The decrease in carryover in FY 2021 was primarily driven by actual collections being less than estimated in FY 2021.

## K. Non-User Fee Appropriations

For FDA to obligate user fees collected under GDUFA, a certain amount of non-user fee appropriations must be allocated for human generic drug activities for each fiscal year. This is often referred to as a “non-user fee spending trigger”.<sup>11</sup>

<sup>11</sup> The GDUFA program requires a minimum spending from appropriations, excluding user fees. The minimum allocation from non-user fee appropriations is \$97,000,000 multiplied by the adjustment factor defined in section 744A(3) of the FD&C Act applicable to the fiscal year involved.

Table 6 presents the actual non-user fee spending triggers for FY 2018 through FY 2022.

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

| FY 2018       | FY 2019       | FY 2020       | FY 2021       | FY 2022       |
|---------------|---------------|---------------|---------------|---------------|
| Actual        | Actual        | Actual        | Actual        | Actual        |
| \$103,558,073 | \$105,671,800 | \$108,337,360 | \$110,248,454 | \$111,551,649 |

Numbers have been rounded to the nearest dollar

The non-user fee spending trigger amount, i.e., the amount of non-user fee appropriations that must be allocated for human generic drug activities, is determined by multiplying \$97,000,000 by the adjustment factor for the fiscal year. See **Note 7** for more details on the adjustment factor.

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

## L. Planned Hiring

During the course of GDUFA II, FDA focused on building staff capacity to manage the increasing program workload, meet performance goals, and deliver on new commitments funded in GDUFA II. The agency hired as needed to maintain staffing for the GDUFA program given attrition and the resources available to the program.

## ***Management Assurance***

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### M. 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.

## N. Risks and Challenges

### Financial Risks and Mitigation

As is the case with all financial programs, there are certain financial risks and challenges that exist with FDA's user fee programs. These risks and challenges can vary from program to program, with some being in FDA's control and some out of FDA's control. An example of a shared financial risk across all user fee programs is that FDA cannot obligate funds in advance of receiving the funds (either appropriated user fee collections or non-user fee appropriations). FDA can only estimate 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 is considerably lower than anticipated. Below is a listing of foreseeable risks associated with the collections and obligations of user fee funds for which FDA has identified contingency plans in order to move forward in the best interests of the program.

- **Under-Executing Planned Spend:** Spending of GDUFA budgetary resources has at times been slowed 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 continued to enhance its planning and execution around the hiring of staff and contract actions in the fourth year of the reauthorization.
- **Uncertainty of Non-User Fee Appropriations Levels:** It is difficult to predict the amount of non-user fee appropriations that will be approved by Congress, which creates planning challenges as non-user fee fund levels are often uncertain for much of the fiscal year. With Continuing Resolutions (CR) becoming more prevalent, FDA has been required to spend at or slightly below levels from the prior authorized fiscal year during the CR period, thus limiting its ability to spend the non-user fee appropriations from the onset.
- **Lapse in Non-User Fee Appropriations:** FDA is maintaining a certain level of carryover, which can be used to preserve program operations for a limited time in the event of a lapse in appropriations. For the GDUFA program, FDA believes it needs roughly 8 to 12 weeks of carryover to help mitigate this risk.
- **Under Collecting and Over-Collecting:** If the number of fee-paying units varies from FDA's estimate, there may be an excess or deficit in receipt of targeted revenue. When FDA under collects user fees, it leverages its carryover balance to maintain continuity in operations. In FY 2021 FDA collected 96 percent of its target revenue, requiring use of the carryover to fill budget gaps. When FDA over collects, the carryover may increase beyond estimated levels. In addition, FDA monitors collections throughout the fiscal year, and the UFFMC and other FDA senior leaders determine how to mitigate any instances when user fee revenue deviates from forecasted estimates.

- **Global Health Pandemic:** There is currently some degree of uncertainty regarding the potential long term impact of COVID-19 on collections and application submissions. FDA is continually monitoring these impacts and will seek to address financial ramifications as warranted.

In addition to these mitigation strategies, FDA implemented Integrated Budget and Acquisition Planning System (IBAPS) to enable greater and more timely insight into budget activity across the Agency. IBAPS improves the accuracy and availability of budget and acquisition information that enables FDA to better plan, forecast, track, and analyze the data to make better informed decisions about the best use of its resources.

### **Strategic Challenges**

FDA acknowledges that anticipated workload is the greatest unknown and most impactful variable throughout GDUFA II. If industry and FDA can accurately predict GDUFA workload, then the financial management of the program will avoid similar challenges it faced in GDUFA I.

# Appendices

## A. Allowable and Excluded Costs for the GDUFA Program

Section 744A(9) of the FD&C Act defines the term “human generic drug activities” as specified activities associated with generic drugs and inspection of facilities associated with generic drugs. In summary, costs related to the following have been attributed to human generic drug activities:

| Included Activities   |  |
|---|--|
| <ol style="list-style-type: none"> <li>1. The activities necessary for the review of generic drug submissions, including review of DMFs referenced in such submissions.</li> <li>2. The issuance of—               <ol style="list-style-type: none"> <li>a. Approval letters which approve ANDAs or prior approval supplements to such applications.</li> <li>b. Complete response letters which set forth in detail the specific deficiencies in such applications and, where appropriate, the actions necessary to place such applications in condition for approval.</li> </ol> </li> <li>3. The issuance of letters related to Type II active pharmaceutical ingredient DMFs which:               <ol style="list-style-type: none"> <li>a. Set forth in detail, the specific deficiencies in such submissions, and where appropriate, the actions necessary to resolve those deficiencies; or</li> <li>b. Document that no deficiencies need to be addressed.</li> </ol> </li> <li>4. Inspections related to generic drugs.</li> <li>5. Monitoring of research conducted in connection with the review of generic drug submissions and DMFs.</li> </ol> | <ol style="list-style-type: none"> <li>6. Post-market safety activities with respect to drugs approved under abbreviated new drug applications or supplements, including the following activities:               <ol style="list-style-type: none"> <li>a. Collecting, developing, and reviewing safety information on approved drugs including adverse event reports.</li> <li>b. Developing and using improved adverse-event data collection systems, including information technology systems.</li> <li>c. Developing and using improved analytical tools to assess potential safety problems including access to external databases.</li> <li>d. Implementing and enforcing section 505(o) (relating to post-approval studies and clinical trials and labeling changes) and section 505(p) (relating to risk evaluation and mitigation strategies) insofar as those activities relate to abbreviated new drug applications.</li> <li>e. Carrying out section 505(k)(5) (relating to adverse-event reports and post-market safety activities).</li> </ol> </li> <li>7. Regulatory science activities related to generic drugs.</li> </ol> |

Section 744A(12) of the FD&C Act defines the term “resources allocated for human generic drug activities” as expenses for the following:

| Included Expenses  |
|--|
| <ol style="list-style-type: none"> <li>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;</li> <li>2. Management of information and the acquisition, maintenance, and repair of computer resources;</li> <li>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</li> <li>4. Collecting fees under subsection 744B of the FD&amp;C Act and accounting for resources allocated for the review of abbreviated new drug applications and supplements and inspection related to generic drugs.</li> </ol> |

The GDUFA program excludes costs related to the following:

| Excluded Activities   |
|---|
| 1. All activities necessary for the review of new drug applications (NDAs), biologic license applications (BLAs), and investigational new drugs (INDs) for drugs that will not be approved under ANDAs. |
| 2. The issuance of correspondence unrelated to abbreviated new drug submissions, pre-ANDAs, or prior approval supplements.  |
| 3. Inspections unrelated to human generic drugs.  |
| 4. Monitoring of research unrelated to human generic drug submissions and DMFs.   |
| 5. Post-market safety activities apart from those drugs approved under ANDAs or supplements.  |

## B. User Fee Program History

The FD&C Act's GDUFA provisions authorize FDA to assess and collect user fees from the generic drug product industry to supplement the non-user fee appropriations that the Agency spends on human generic drug activities. FDA spends appropriated fee revenues and non-user fee appropriations to hire, support, and maintain personnel for the generic drug review program to ensure the American public has access to safe and high-quality generic drugs and generic drug products.

Originally authorized in [2012](#), GDUFA was reauthorized by FDARA in 2017 (GDUFA II) with the support of the generic drug industry, public stakeholders, Congress, and the Administration.

## C. Financial Notes

### Note 1. Annual Target Revenue Methodology

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

### Note 2. 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 for which obligated funds were not expended.

### Note 3. Pay and Operating Costs

Pay and operating costs associated with the GDUFA program are based on obligations attributed to CBER, CDER, ORA and HQ.

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

### Note 4. Rent Costs

The GSA charges rent to FDA for the Federal buildings that FDA occupies. This rent is charged at different rates depending on the type and location of the space provided. Since rent is an essential

support cost for human generic drug activities, a portion of those charges is paid from non-user fee appropriations and a portion is paid from GDUFA fees. Also included in this account are recurring costs that FDA pays to non-Federal sources under the delegation of direct lease and service authority. These services include rental of space, and all recurring services for building operations such as overtime utilities, janitorial services, guards, and ground maintenance. The amount of rent and rent related costs each Center pays is directly related to the square footage occupied by that Center.

#### **Note 5. Shared Service Costs**

FDA has several shared service organizations, located with the WCF, that provide support across the user fee programs. Several new organizations joined the WCF in FY 2021. The shared service organizations in FY -20212021 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 budget resources. The agency budget is comprised of several appropriation accounts including: Salaries and Expenses, Revolving Fund for Color Certification and other Services, Cooperative Research and Development Agreement, Contingency Fund, Building and Facilities, and Royalties.
- **Office of Finance, Budget, Acquisitions, and Planning:** Leads FDA's budget, acquisitions, and financial management functions while ensuring the financial integrity of FDA's resources.
- **Office of Security Operations:** Develops and implements the Agency-wide security policies and programs by providing leadership and guidance to managers and staff on all aspects of security. Administers vital security functions that contribute to the Agency's mission of protecting the public health by enhancing the safety and security of all personnel, facilities, and information.
- **Office of Laboratory Safety:** Reinforces FDA's expectations for safety and laboratory security, enhances communications among FDA safety staff, and provides program support.
- **Office of Ethics and Integrity:** Protects the integrity of FDA's programs and operations by promoting an ethical culture and ensuring compliance with applicable federal ethics laws.
- **Office of Enterprise Management Services:** Provides strategic and tactical enterprise-wide services through development and implementation of administrative policies, programs, and initiatives.
- **Office of Human Capital Management:** Provides Human Resource services that promote collaboration and a work environment that is characterized by diversity, fairness, open communication, personal accountability, trust and mutual respect.
- **Office of Talent Solutions:** Provides high quality and efficient Human Resource solutions that enable the FDA to hire a talented and qualified workforce.

- **Office of Planning, Evaluation, and Risk Management:** Partners with FDA leaders to achieve organizational excellence by improving program performance, governance, operational efficiency, and risk management.

#### **Note 6. Future Year Refund Allowance, Set Aside**

If an ANDA is considered not to have been received within the meaning of section 505(j)(5)(A) of the FD&C Act for a cause other than failure to pay user fees, or if the ANDA is withdrawn prior to being received within the meaning of section 505(j)(5)(A), the applicant is eligible for a 75 percent refund of the ANDA filing fee. If an ANDA is initially received under section 505(j)(5)(A), but FDA subsequently determines that the exclusivity period for a listed drug should have prevented the ANDA from being received, the ANDA is no longer considered received under section 505(j)(5)(A), and the applicant is eligible for a full refund of the ANDA filing fee paid.

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

#### **Note 7. Appropriations Adjustment Factor**

FDA must calculate and apply an adjustment factor (defined in section 744A(3) of the FD&C Act). The FD&C Act states, “the term ‘adjustment factor’ means a factor applicable to a fiscal year that is the Consumer Price Index for all urban consumers (all items; United States city average) for October of the preceding fiscal year divided by such Index for October 2011.”

#### **Note 8. Final Year Adjustment**

For FY 2022, FDA may, in addition to the inflation adjustment, further increase the fee revenue and fees established if such an adjustment is necessary to provide for not more than 3 months of operating reserves of carryover user fees for human generic drug activities for the first 3 months of FY 2023.