Public Meeting on Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments

Public Meeting
June 8, 2023
9:30 – 10:30 AM

9:30 – 9:40 AM

Welcome and Introduction

Benjamin Moncarz
Chief Financial Officer
Office of Finance, Budget, Acquisitions, and Planning

Agenda

Topic	Presenter	Time
Welcome and Introduction	**Benjamin Moncarz** Chief Financial Officer Office of Finance, Budget, Acquisitions, and Planning	9:30 – 9:40 AM
Update on 5-Year Financial Plans	**Funmi Ariyo** Acting Director, User Fees Support Staff, Office of Financial Management Office of Finance, Budget, Acquisitions, and Planning	9:40 – 10:00 AM
Resource Capacity Planning (RCP) Implementation Updates	**Bethany Rue** Data Scientist, Resource Capacity Planning Staff, Office of Program and Strategic Analysis Center for Drug Evaluation and Research	10:00 – 10:20 AM
Wrap Up & Additional Information	**Monica Ellerbe** Director, Business Management Services Office of Finance, Budget, Acquisitions, and Planning	10:20 – 10:30 AM
	Total Time	**60 minutes**

9:40 – 10:00 AM

Update On 5-Year Financial Plans

Funmi Ariyo
Acting Director, User Fees Support Staff, Office of Financial Management
Office of Finance, Budget, Acquisitions, and Planning

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$1,200,129,000**	**$1,200,129,000**	**$1,310,319,000**	**$1,404,214,000**	**$1,435,422,000**	**$1,484,654,000**	**$1,531,320,000**
Net Collections	$1,200,129,000	$1,159,139,951	$1,310,319,000	$1,404,214,000	$1,435,422,000	$1,484,654,000	$1,531,320,000
Recoveries	$12,000,000	$13,354,888	$12,000,000	$12,000,000	$12,000,000	$12,000,000	$12,000,000
Total Carryover, Beginning of Year	$244,902,650	$244,902,650	$287,669,825	$305,600,285	$364,444,923	$401,744,820	$416,599,777
Total Budgetary Resources	**$1,457,031,650**	**$1,417,397,489**	**$1,609,988,825**	**$1,721,814,285**	**$1,811,866,923**	**$1,898,398,820**	**$1,959,919,777**

User Fee Obligations	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Payroll & Operating							
CBER	$163,802,977	$160,804,109	$209,746,098	$236,453,105	$245,734,170	$254,332,543	$260,096,994
CDER	$753,055,633	$712,050,050	$814,107,273	$864,358,474	$905,946,034	$965,202,138	$1,034,957,137
CDRH	$4,239,557	$3,176,215	$4,372,971	$4,523,393	$4,613,860	$4,706,138	$4,800,260
ORA	$9,312,383	$7,671,485	$9,482,846	$9,809,037	$10,005,218	$10,205,322	$10,409,429
HQ	$55,401,955	$54,684,720	$63,855,459	$59,969,072	$58,167,761	$59,296,712	$60,443,125
Total Rent	$63,162,874	$59,443,256	$59,306,768	$33,906,783	$34,245,850	$34,588,309	$34,934,192
Total Shared Services	$124,845,109	$131,897,830	$143,517,124	$148,349,499	$151,409,210	$153,467,880	$155,149,735
Total Obligations	**$1,173,820,488**	**$1,129,727,665**	**$1,304,388,539**	**$1,357,369,362**	**$1,410,122,103**	**$1,481,799,042**	**$1,560,790,873**

Carryover	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$283,211,161	$287,669,825	$305,600,285	$364,444,923	$401,744,820	$416,599,777	$399,128,905
Unappropriated Amounts	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Future Year Refunds Allowance, Set Aside	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)	($20,000,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$184,360,166**	**$188,818,830**	**$206,749,290**	**$265,593,928**	**$302,893,825**	**$317,748,782**	**$300,277,910**

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$40,040,000**	**$40,040,000**	**$41,600,000**	**$48,834,000**	**$48,737,000**	**$53,425,000**	**$54,450,000**
Net Collections	$40,040,000	$43,106,548	$41,600,000	$48,834,000	$48,737,000	$53,425,000	$54,450,000
Recoveries	$600,000	$333,532	$600,000	$600,000	$600,000	$600,000	$600,000
Total Carryover, Beginning of Year	$45,956,772	$45,956,772	$43,317,275	$30,567,030	$26,598,901	$21,018,020	$18,925,254
Total Budgetary Resources	**$86,596,772**	**$89,396,852**	**$85,517,275**	**$80,001,030**	**$75,935,901**	**$75,043,020**	**$73,975,254**

User Fee Obligations	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Payroll & Operating							
CBER	$310,405	$0	$762,722	$789,444	$805,233	$821,337	$837,764
CDER	$36,143,181	$36,930,952	$45,188,359	$45,250,050	$46,286,971	$47,357,711	$48,449,865
ORA	$1,500,956	$1,212,289	$1,516,326	$1,569,450	$1,600,839	$1,632,856	$1,665,513
HQ	$1,310,362	$1,307,276	$1,957,880	$1,436,568	$1,458,834	$1,486,019	$1,513,544
Total Rent	$1,567,019	$1,372,237	$1,372,237	$272,514	$275,239	$277,992	$280,772
Total Shared Services	$2,947,378	$5,256,823	$4,152,722	$4,266,103	$4,308,764	$4,351,852	$4,395,370
Total Obligations	**$43,779,301**	**$46,079,577**	**$54,950,245**	**$53,584,129**	**$54,735,881**	**$55,927,766**	**$57,142,828**

Carryover	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$42,817,470	$42,317,275	$30,567,030	$26,416,901	$21,018,020	$18,925,254	$16,832,426
Future Year Refunds Allowance, Set Aside	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)	($1,000,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$41,817,470**	**$41,317,275**	**$29,567,030**	**$25,416,901**	**$20,018,020**	**$17,925,254**	**$15,832,426**

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$539,656,000**	**$539,656,000**	**$582,500,000**	**$595,034,000**	**$606,934,000**	**$619,073,000**	**$631,454,000**
Net Collections	$539,656,000	$545,842,834	$582,500,000	$595,034,000	$606,934,000	$619,073,000	$631,454,000
Recoveries	$7,000,000	$6,132,460	$10,000,000	$10,000,000	$10,000,000	$10,000,000	$10,000,000
Total Carryover, Beginning of Year	$127,223,404	$127,223,404	$131,211,761	$134,626,041	$134,486,874	$135,624,692	$128,428,564
Total Budgetary Resources	**$673,879,404**	**$679,198,698**	**$723,711,761**	**$739,660,041**	**$751,420,874**	**$764,697,692**	**$769,882,564**

User Fee Obligations	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Payroll & Operating							
CBER	$1,040,390	$0	$ 1,040,390	$ 1,062,776	$ 1,084,031	$ 1,105,712	$ 1,127,826
CDER	$399,022,266	$377,913,169	$ 403,639,923	$ 426,626,067	$ 435,813,589	$ 453,541,550	$ 462,760,296
ORA	$51,129,752	$46,585,741	$ 53,494,587	$ 56,955,304	$ 58,094,410	$ 59,256,298	$ 60,441,424
HQ	$35,060,496	$32,634,275	$ 37,086,872	$ 35,921,779	$ 35,350,840	$ 36,057,723	$ 36,791,365
Total Rent	$26,576,719	$21,595,013	$ 21,595,013	$ 12,242,365	$ 12,364,788	$ 12,488,436	$ 12,613,320
Total Shared Services	$64,738,821	$69,258,739	$ 72,228,936	$ 72,364,876	$ 73,088,524	$ 73,819,410	$ 74,557,604
Total Obligations	**$577,568,444**	**$547,986,937**	**$589,085,720**	**$605,173,167**	**$615,796,182**	**$636,269,129**	**$648,291,835**

Carryover	FY 2022		FY 2023	FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$96,310,960	$131,211,761	$134,626,041	$134,486,874	$135,624,692	$128,428,564	$121,590,729
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($4,000,000)	($4,000,000)	($4,000,000)	($4,000,000)	($4,000,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$92,310,960**	**$127,211,761**	**$130,626,041**	**$130,486,874**	**$131,624,692**	**$124,428,564**	**$117,590,729**

10:00 – 10:20 AM

Resource Capacity Planning Implementation Updates

Bethany Rue
Data Scientist, Resource Capacity Planning Staff, Office of Program and Strategic Analysis
Center for Drug Evaluation and Research

PDUFA VII, BsUFA III, and GDUFA III include a set of Resource Capacity Planning commitments (1 of 2)

FDA is committed to ensuring the sustainability of PDUFA[1], BsUFA[2], and GDUFA[3] program resources and enhancing operational agility of the respective user fee programs. FDA will build on financial enhancements included in PDUFA VI, BsUFA II, and GDUFA II to ensure optimal use of user fee resources and the alignment of staff to workload through the continual maturation and assessment of the Agency's resource capacity planning capability.

1. Implementation Plan

1. FDA will publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented for the user fee programs by the end of the second quarter of FY 2023. The implementation plan will address topics such as: 1) the continued implementation of the Agency's resource capacity planning capability; and 2) the integration of resource capacity planning analyses in the Agency's resource and operational decision-making processes.

2. Capacity Planning Adjustment

2. FDA will work to continually improve the Capacity Planning Adjustment (CPA) for PDUFA and BsUFA. FDA will implement the CPA for GDUFA starting for FY 2024 fees. FDA will work to continually improve time reporting and its utilization in the CPA.

[1] PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027
[2] Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027
[3] GDUFA Reauthorization Performance Goals and Program Enhancements Fiscal Years 2023-2027

PDUFA VII, BsUFA III, and GDUFA III include a set of Resource Capacity Planning commitments (2 of 2)

3. Independent Assessment

3. FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of the resource capacity planning capability by the end of FY 2025. The assessment will include: 1) the ability of the CPA to forecast resource needs in the respective user fee programs including an assessment of the scope of the workload drivers included in the CPA; 2) opportunities for enhancement of time reporting toward informing resource needs; and 3) the integration and utilization of resource capacity planning information within resource and operational decision-making processes of the respective user fee programs.

4. Financial Reporting

4. FDA will continue to document in the annual user fee reports how CPA fee revenues are being utilized for PDUFA and BsUFA and will begin to document how CPA fee revenues are being utilized for GDUFA beginning in FY 2024.

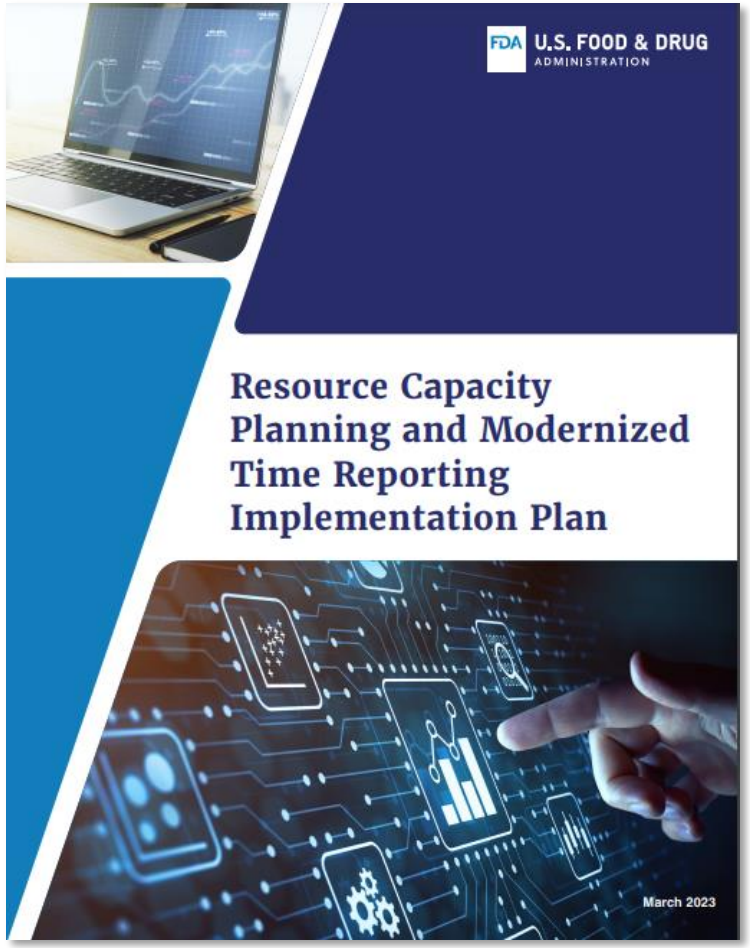
Resource Capacity Planning and Modernized Time Reporting Implementation Plan

Commitment:

FDA will publish an implementation plan that will describe how resource capacity planning and time reporting will continue to be implemented. The implementation plan will address topics such as: 1) the continued implementation of the Agency's resource capacity planning capability; and 2) the integration of resource capacity planning analyses in the Agency's resource and operational decision-making processes.

How We Delivered On This:

- The Resource Capacity Planning and Modernized Time Reporting Implementation Plan was published on FDA's website before the March 31, 2023 deadline
- The contents of the plan were developed by stakeholders across CDER, CBER, and ORA and covers the PDUFA, BsUFA, and GDUFA programs
- FDA will provide annual updates on the FDA website on the Agency's progress relative to the activities detailed in this implementation plan by the end of the second quarter of each subsequent fiscal year



Topics covered in the Implementation Plan

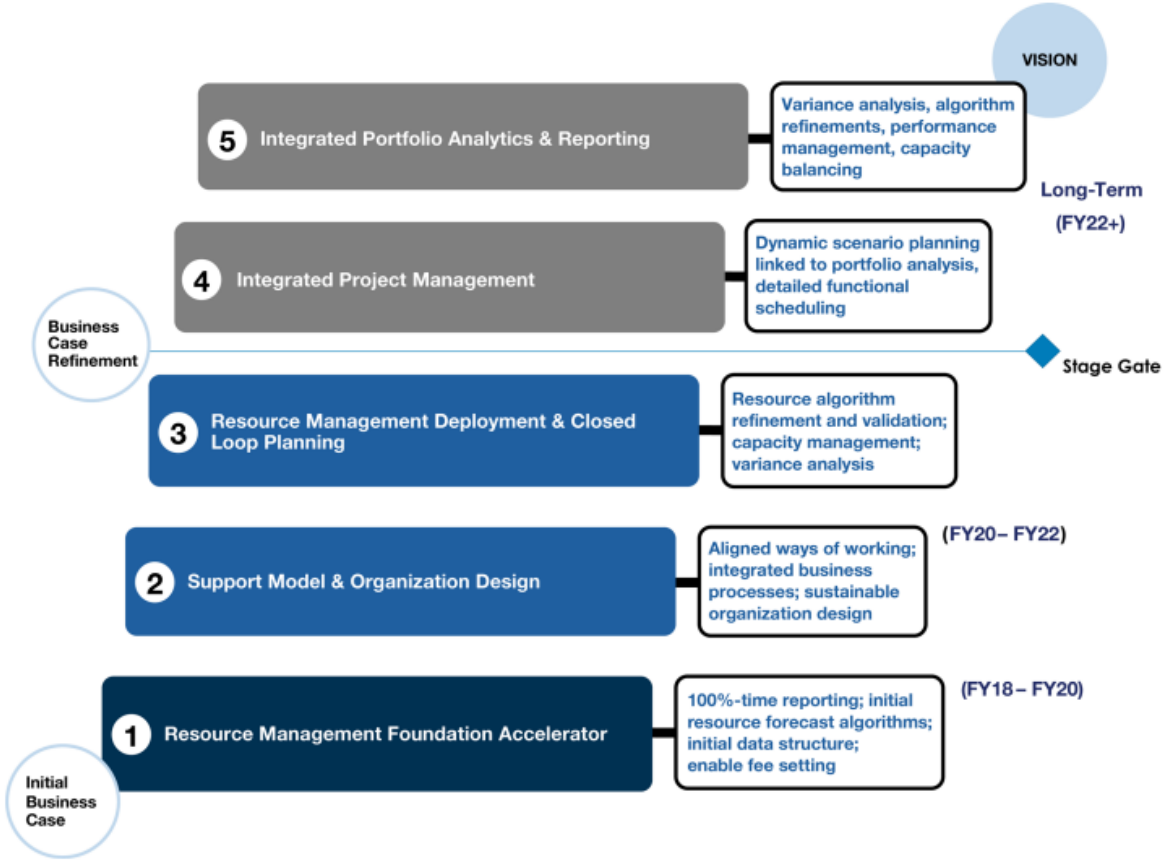
- The Implementation Plan detailed the development, management, and optimization of RCP capabilities. Topics covered include:

1. Feasibility Assessment of Integrated Project Management, and Portfolio Analytics & Reporting
2. Updated RCP Concept of Operations
3. Continual Improvement of Time Reporting
4. Continual Improvement of the CPA (PDUFA & BsUFA) / Implementation of the CPA (GDUFA)
5. Integration RCP Analyses into Financial and Operational Decision-Making Processes

Feasibility Assessment of Integrated Project Management, and Portfolio Analytics & Reporting

- The first RCP Implementation Plan was published during the previous authorization period (FY 2018 – FY 2022). In this plan, FDA articulated five phases of implementation.
  - The first three phases have been largely implemented and are undergoing continual improvement

- For the current authorization period, FDA will engage a contractor to conduct a feasibility study of Phases 4-5 of the original implementation plan which include integrated project management and portfolio analytics and reporting.
  - This feasibility assessment will be conducted in FY 2024



Updated RCP Concept of Operations

- During the previous authorization period (FY 2018 – FY2022), FDA focused on the development of the foundational RCP capability through a collaborative approach across CDER and CBER

- In the current authorization period, FDA will focus on sustaining, refining, and expanding the RCP capability for CDER and CBER

    - In addition, this effort will include a review of the existing support and operating model and subsequent updates to the cross-center governance as needed to align ORA

Continual Improvement of Time Reporting

- CDER and CBER established modernized time reporting in the previous authorization cycle. CBER is transitioning to Insight Time Reporting.
- ORA has implemented full, modernized time reporting using ITR
- FDA will continue to work to ensure categories included in ITR are consistent with evolving program needs

Continual Improvement of the CPA (PDUFA & BsUFA) / Implementation of the CPA (GDUFA)

- CDER and CBER will work to continually improve the PDUFA and BsUFA CPA
- CDER and ORA will work to implement the GDUFA CPA
- Further details on the CPA to be discussed in later slides

Integrating RCP Analyses into Financial and Operational Decision-Making Processes

- Over the current authorization period, FDA will leverage the RCP foundation by adapting existing financial and resource management processes to utilize RCP data and analyses
  - By integrating RCP analyses into these processes, FDA will enable more proactive management of user fee funding and resources

- FDA will coordinate with internal stakeholders to plan and prioritize opportunities to integrate RCP analyses into existing financial and resource management processes

The Capacity Planning Adjustment

Commitment:

FDA will work to continually improve the Capacity Planning Adjustment (CPA) for PDUFA and BsUFA. FDA will implement the CPA for GDUFA starting for FY 2024 fees. FDA will work to continually improve time reporting and its utilization in the CPA.

How We Are Delivering On This:

- PDUFA and BsUFA CPAs were implemented in the previous authorization period. In the current authorization period, FDA will identify opportunities for:
  - Refinements to models to account for program dynamics
  - Continual iterations to enhance model predictions
- The GDUFA CPA will be implemented in the current authorization cycle which is derived by the methodology developed and evaluated during GDUFA II.
  - The CDER portion of the GDUFA CPA will be implemented for FY 2024 fees
  - The ORA portion of the GDUFA CPA will aim to be implemented for FY 2025 fees to allow for sufficient time reporting data to be collected
- After the GDUFA CPA implementation, FDA will work to continually improve the GDUFA CPA by engaging the same continual improvement process established for PDUFA and BsUFA.

Independent Assessment of RCP, the CPA, & Modernized Time Reporting

Commitment:

FDA will obtain through a contract with an independent accounting or consulting firm an evaluation of the resource capacity planning capability by the end of FY 2025. The assessment will include: 1) the ability of the CPA to forecast resource needs in the respective user fee program including an assessment of the scope of the workload drivers included in the CPA; 2) opportunities for enhancement of time reporting toward informing resource needs; and 3) the integration and utilization of resource capacity planning information within resource and operational decision-making processes of the respective user fee programs.

How We Will Deliver On This:

- FDA will engage with a contractor to conduct an evaluation of RCP, the CPA, and Modernized Time Reporting. The report will be published on FDA's website by the end of FY 2025.
- The contractor will provide options and recommendations in the evaluation regarding the continued enhancements of RCP, the CPA, time reporting, and integration and utilization of RCP to inform resource and operational decision-making within each respective UFA program.
- The evaluation findings and any related recommendations will be discussed at the FY 2026 PDUFA, BsUFA, and GDUFA 5-year financial plan public meetings, respectively.

Allocation and Reporting of CPA Funds

Commitment:

FDA will continue to document in the annual user fee reports how CPA fee revenues are being utilized for PDUFA and BsUFA and will begin to document how CPA fee revenues are being utilized for GDUFA beginning in FY 2024.

How We Are Delivering On This:

- A process has been established to ensure distribution of revenue generated by the CPA are allocated to review components in CDER and CBER. Once ORA components of the GDFUA CPA are implemented, the established process will be extended to ORA
- Documentation added to annual financial reports on the distribution of these resources

10:20 – 10:30 AM

Wrap Up and Additional Information

Monica Ellerbe
Director, Business Management Services
Office of Finance, Budget, Acquisitions, and Planning

Wrap Up and Additional Information

Public Comments

To submit a public comment following this meeting, please follow these steps:

1. Go to Regulations.gov
2. Use Docket No. FDA-2019-N-1875 to locate this meeting
3. Submit your comment

You will have until **July 8, 2023, at 11:59 PM** Eastern Time to submit a comment.

Meeting Materials

To access the materials from this meeting, please visit the FDA.gov webpage listed below**:**

- 2023 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments - 06/08/2023 | FDA