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 6, 2024
9:30 – 10:40 AM

9:35 – 9:40 AM

Welcome and Introduction

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

Agenda

Topic	Presenter	Time
Begin Meeting	**Kichelle Joseph** Acting Director, Business Management Services Office of Finance, Budget, Acquisitions, and Planning	9:30 – 9:35 AM
Welcome and Introduction	**Benjamin Moncarz** Chief Financial Officer Office of Finance, Budget, Acquisitions, and Planning	9:35 – 9:40 AM
Update on 5-Year Financial Plans	**Olufunmilayo Ariyo** Director, User Fees Support Staff, Office of Financial Management Office of Finance, Budget, Acquisitions, and Planning	9:40 – 10:00 AM
PDUFA Fee-Setting Process and Drivers of the Application Fee	**Josh Barton** Director, Resource Capacity Planning Staff, Office of Program and Strategic Analysis Center for Drug Evaluation and Research	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	10:20 – 10:30 AM
Wrap Up & Additional Information	**Kichelle Joseph** Acting Director, Business Management Services Office of Finance, Budget, Acquisitions, and Planning	10:30 – 10:40 AM
	Total Time	**70 minutes**

9:40 – 10:00 AM

Update On 5-Year Financial Plans

Olufunmilayo Ariyo
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 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$1,310,319,000**	**$1,310,319,000**	**$1,422,104,000**	**$1,472,210,000**	**$1,541,682,000**	**$1,610,463,000**
Net Collections	$1,310,319,000	$1,222,888,088	$1,452,104,000	$1,472,210,000	$1,541,682,000	$1,610,463,000
Recoveries	$12,000,000	$16,400,359	$12,567,000	$12,567,000	$12,567,000	$12,567,000
Total Carryover, Beginning of Year	$287,669,825	$287,669,825	$275,515,520	$351,685,404	$375,284,588	$402,087,721
Total Budgetary Resources	**$1,609,988,825**	**$1,526,958,272**	**$1,740,186,520**	**$1,836,462,404**	**$1,929,533,588**	**$2,025,117,721**

User Fee Obligations	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$209,746,098	$195,551,430	$242,117,202	$270,255,052	$286,018,792	$299,438,447
CDER	$814,107,273	$782,635,425	$881,775,355	$915,783,660	$955,429,408	$996,697,448
CDRH	$4,372,971	$2,647,796	$3,682,045	$4,874,791	$5,075,471	$5,284,413
ORA	$9,482,846	$8,090,718	$10,181,990	$10,601,152	$11,037,570	$11,491,953
HQ	$63,855,459	$62,835,758	$54,610,302	$54,772,115	$56,916,838	$57,771,651
Total Rent	$59,306,768	$48,137,237	$28,672,907	$28,959,636	$29,249,233	$29,541,725
Total Shared Services	$143,517,124	$151,544,388	$167,461,315	$175,931,410	$183,718,556	$191,428,874
Total Obligations	**$1,304,388,539**	**$1,251,442,752**	**$1,388,501,116**	**$1,461,177,816**	**$1,527,445,868**	**$1,591,654,511**

Carryover	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$305,600,285	$275,515,520	$351,685,404	$375,284,588	$402,087,721	$433,463,210
Unappropriated Amounts	($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)	($25,229,000)	($25,229,000)	($25,229,000)	($25,229,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$206,749,290**	**$176,664,525**	**$247,605,409**	**$271,204,593**	**$298,007,726**	**$329,383,215**

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$41,600,000**	**$41,600,000**	**$31,019,000**	**$53,347,000**	**$55,731,000**	**$58,216,000**
Net Collections	$41,600,000	$59,629,003	$31,019,000	$53,347,000	$55,731,000	$58,216,000
Recoveries	$600,000	$1,014,458	$590,000	$590,000	$590,000	$590,000
Total Carryover, Beginning of Year	$43,317,275	$43,317,275	$40,994,759	$14,245,046	$13,636,964	$13,089,641
Total Budgetary Resources	**$85,517,275**	**$103,960,736**	**$72,603,759**	**$68,182,046**	**$69,957,964**	**$71,895,641**

User Fee Obligations	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$762,722	$82,007	$800,291	$750,221	$777,035	$813,054
CDER	$45,188,359	$50,009,960	$49,752,200	$45,955,805	$47,945,809	$50,151,897
ORA	$1,516,326	$1,145,055	$1,621,111	$1,491,474	$1,547,672	$1,619,310
HQ	$1,957,880	$1,814,687	$987,132	$940,446	$972,679	$959,969
Total Rent	$1,372,237	$1,079,676	$255,388	$257,941	$260,522	$263,126
Total Shared Services	$4,152,722	$8,834,592	$4,942,041	$5,149,019	$5,364,665	$5,589,342
Total Obligations	**$54,950,245**	**$62,965,977**	**$58,358,162**	**$54,544,905**	**$56,868,382**	**$59,396,699**

Carryover	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	**$30,567,030**	**$40,994,759**	**$14,245,046**	**$13,636,964**	**$13,089,641**	**$12,498,090**
Future Year Refunds Allowance, Set Aside	($1,000,000)	($1,000,000)	($873,000)	($873,000)	($873,000)	($873,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$29,567,030**	**$39,994,759**	**$13,372,046**	**$12,763,964**	**$12,216,641**	**$11,625,090**

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Target Revenue	**$582,500,000**	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$665,439,000**	**$693,014,000**
Net Collections	$582,500,000	$551,653,777	$613,538,000	$638,962,000	$665,439,000	$693,014,000
Recoveries	$10,000,000	$7,656,327	$10,000,000	$6,775,000	$6,775,000	$6,775,000
Total Carryover, Beginning of Year	$131,211,761	$131,211,761	$120,195,906	$114,145,103	$117,306,853	$133,869,683
Total Budgetary Resources	**$723,711,761**	**$690,521,865**	**$743,733,906**	**$759,882,103**	**$789,520,853**	**$833,658,683**

User Fee Obligations	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Payroll & Operating						
CBER	$1,040,390	$248,671	$1,110,810	$1,136,822	$1,163,137	$1,189,632
CDER	$403,639,923	$388,753,701	$449,387,722	$458,844,123	$468,227,809	$477,603,199
ORA	$53,494,587	$49,061,927	$60,069,858	$61,302,937	$62,545,705	$63,786,647
HQ	$37,086,872	$34,219,152	$31,926,538	$32,388,628	$32,945,730	$32,189,941
Total Rent	$21,595,013	$15,134,245	$9,430,213	$9,524,516	$9,619,761	$9,715,958
Total Shared Services	$72,228,936	$82,908,264	$77,663,676	$79,377,917	$81,149,020	$82,928,287
Total Obligations	**$589,085,720**	**$570,325,960**	**$629,588,817**	**$642,574,943**	**$655,651,162**	**$667,413,664**

Carryover	FY 2023		FY 2024	FY 2025	FY 2026	FY 2027
	Estimate	Actual	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	$134,626,041	$120,195,906	$114,145,103	$117,306,853	$133,869,683	$166,244,475
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($4,000,000)	($6,510,000)	($6,510,000)	($6,510,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$130,626,041**	**$116,195,906**	**$110,145,103**	**$110,796,853**	**$127,359,683**	**$159,734,475**

10:00 – 10:20 AM

PDUFA Fee-Setting Process and Drivers of the Application Fee

Josh Barton
Director, Resource Capacity Planning Staff, Office of Program and Strategic Analysis
Center for Drug Evaluation and Research

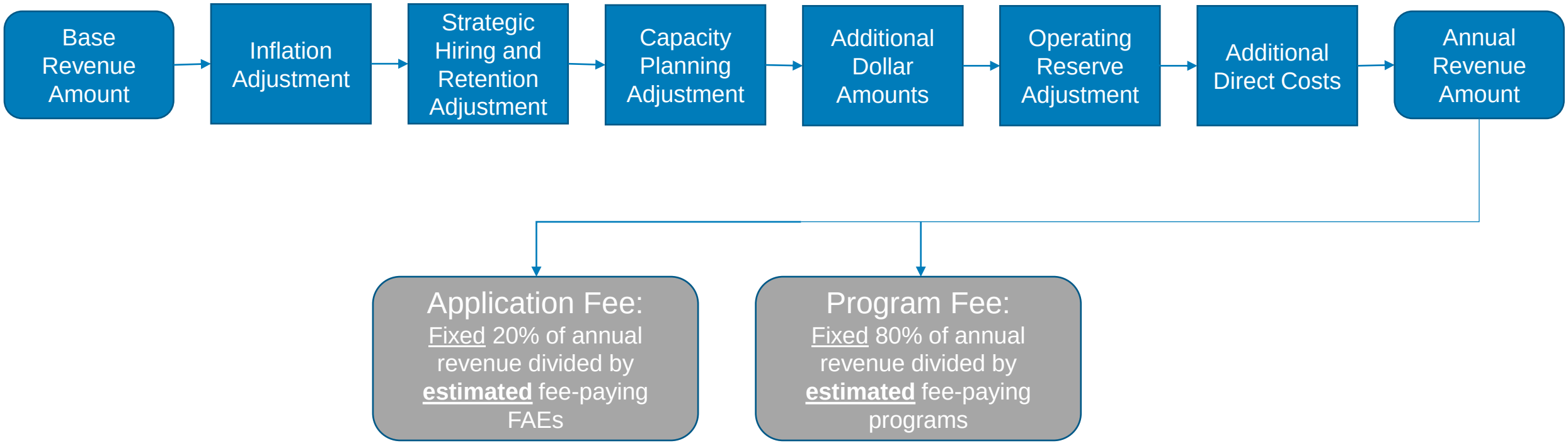
Interested parties have raised concerns regarding the 25% increase in the PDUFA application fee that occurred in FY24

This presentation walks through the PDUFA fee-setting process that was negotiated and agreed to by FDA and industry and which is prescribed in statute.

Fee basics:

- Fees are assessed to certain applications and certain approved products to collect the full annual PDUFA target revenue.
- PDUFA is not a fee-for-service program. Collected fees pay for all allowable activities defined in statute.
  - Application fees do not pay for specific application reviews
  - Program fees do not pay for product-specific activities
  - Many PDUFA-funded activities are not assessed fees: INDs, meetings, supplements reviews, post-market safety activities, regulation and policy development activities, development of product standards, etc.

PDUFA Revenue Setting Process

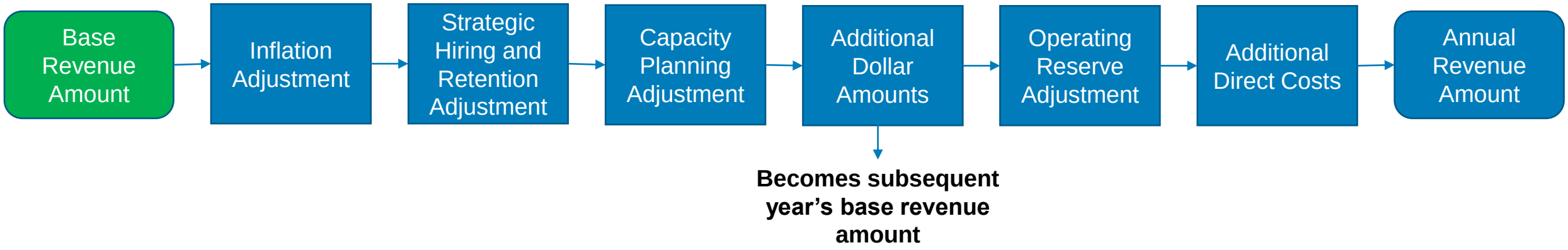


FAE = full-application equivalent

An application requiring covered clinical data counts as one FAE. An application not requiring covered clinical data counts as one-half of an FAE. An application withdrawn before filing, or refused filing, counts as one-fourth of an FAE if the applicant had paid a full application fee, or one eighth of an FAE if the applicant had paid one-half of the full application fee amount.

Reference:
PDUFA Fee-Setting Federal Register Notices
PDUFA Fee-Setting Statutory Language

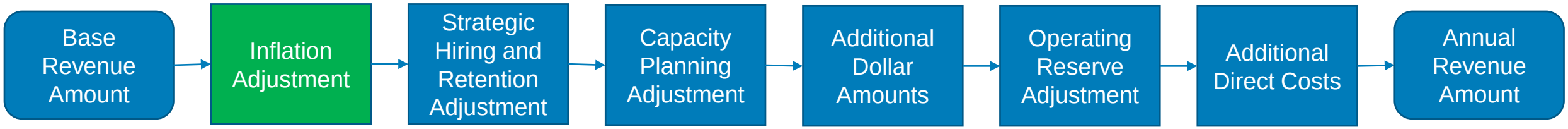
Base Revenue Amount



Not Discretionary

- FY23 amount is written into statute ($1,151,522,958)
- In FY24 – FY27, the base revenue amount is the prior year's total revenue amount minus any adjustment for operating reserve and additional direct costs
  - FY24 = $1,256,844,387
  - FY25 = $1,358,764,346

Inflation Adjustment



Not Discretionary

Inflation Adjustment Percentage = (change in FDA FTE PC&B* costs multiplied by PDUFA's portion of PC&B to total costs) plus (change in DC-area CPI multiplied by PDUFA proportion of non-PC&B costs to total costs)

Where: all values use the average for the first 3 of the preceding 4 fiscal years

FY24 inflation adjustment:

Table 1—FDA Personnel Compensation and Benefits (PC&B) Each Year and Percent Changes

	FY 2020	FY 2021	FY 2022	3-Year average
Total PC&B	$2,875,592,000	$3,039,513,000	$3,165,477,000	
Total FTE	$17,535	$18,501	$18,474	
PC&B per FTE	$163,992	$164,289	$171,348	
Percent Change from Previous Year	7.3063%	0.1811%	4.2967%	3.9280%

Table 2—PC&B as a Percent of Total Cost of the Process for the Review of Human Drug Applications

	FY 2020	FY 2021	FY 2022	3-Year average
Total PC&B	$891,395,106	$959,387,333	$931,302,114	
Total Costs	$1,471,144,928	$1,499,064,056	$1,480,601,875	
PC&B Percent	60.5919%	63.9991%	62.9002%	62.4971%

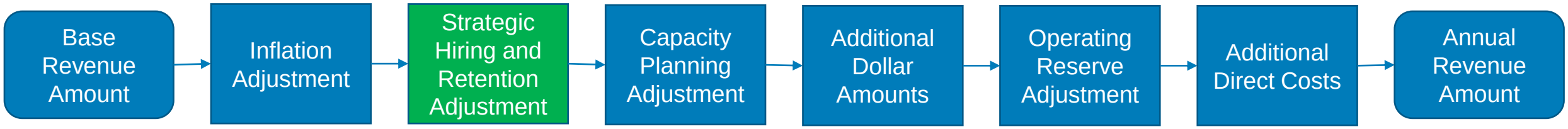
Table 3—Annual and 3-Year Average Percent Change in CPI for Washington-Arlington-Alexandria Area

	FY 2020	FY 2021	FY 2022	3-Year average
Annual CPI	267.16	277.73	296.12	
Annual Percent Change	0.8989%	3.9568%	6.6212%	3.8256%

(3.9280% * 62.4971%) + (3.8256% * (100%-62.4971%)) = 3.8896%

* PC&B = personnel costs and benefits

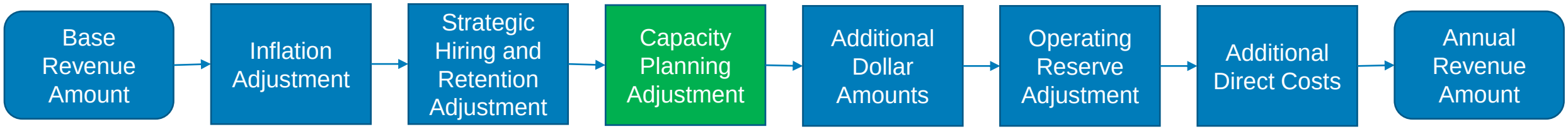
Strategic Hiring and Retention Adjustment



Not Discretionary

- Amounts written into statute pursuant to FDA-Industry agreement to support strategic hiring and retention needs
  - FY23 = $9M
  - FY24 – FY27 = $4M

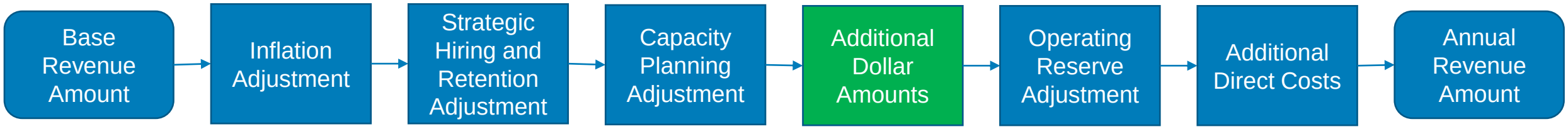
Capacity Planning Adjustment



Some Discretion

- Established per process FDA & industry agreed to in PDUFA VI as a modernization of the PDUFA Workload Adjuster
- Discretion enabled through managerial adjustment process
  - This is an innovation implemented with the new CPA starting in FY21
  - The interim CPA and the workload adjuster resulted in full adjustment regardless of any other factors
  - Enables potential downward adjustment of the CPA-calculated FTE delta based on additional factors, i.e.:
    - Forecast performance
    - Whether forecasts are expected to be sustained
    - Ability to hire in a timely manner
    - Whether other sources of funds are available to support the needed FTEs
  - Managerial adjustment has only resulted in a lowered adjustment

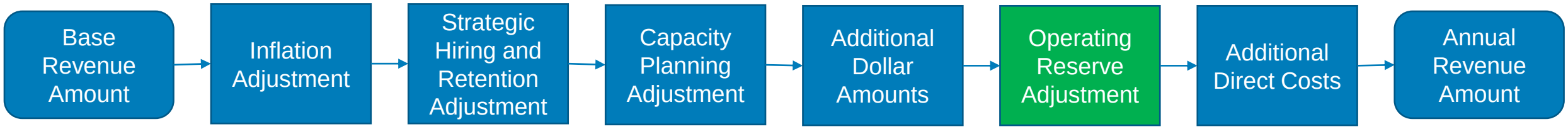
Additional Dollar Amounts



Not Discretionary

- Amounts written into statute pursuant to FDA-Industry agreement to support new personnel as a result of negotiated enhancements
  - $65,773,693 for fiscal year 2023
  - $25,097,671 for fiscal year 2024
  - $14,154,169 for fiscal year 2025
  - $4,864,860 for fiscal year 2026
  - $1,314,620 for fiscal year 2027

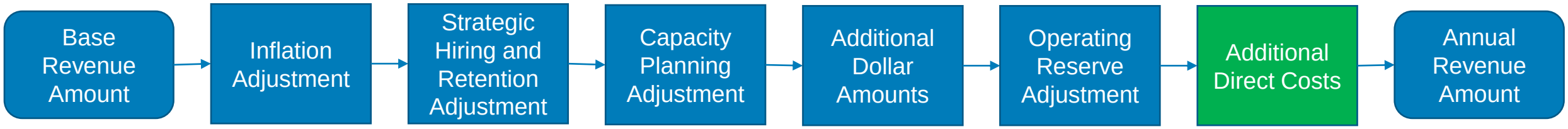
Operating Reserve Adjustment



Bounds are not discretionary

- Maximum operating reserve equals the equivalent of 14 weeks
- Minimum operating reserve phases up from FY23 to FY25:
  - FY23 – 8 weeks
  - FY24 – 9 weeks
  - FY25+ – 10 weeks
- Operating reserve does not include the ~$79M that are considered not available for obligation
- These funds are not included in the base revenue amount for subsequent years

Additional Direct Costs

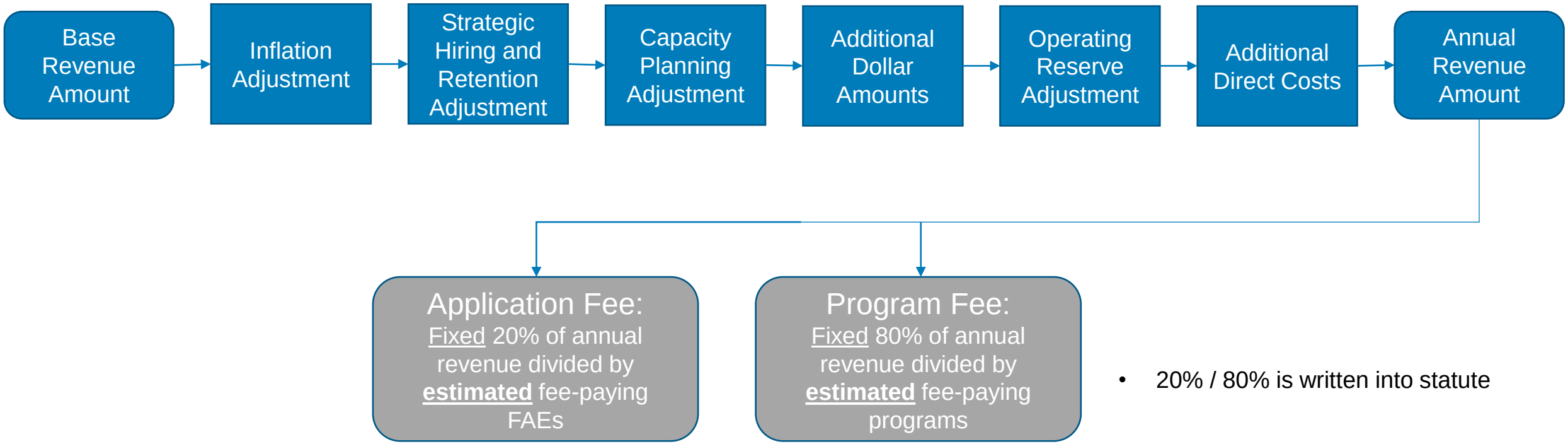


Not Discretionary

- Provide for operating costs associated with PDUFA VII enhancements
  - $44,386,150 for fiscal year 2023
  - $60,967,993 for fiscal year 2024
  - $35,799,314 for fiscal year 2025
  - $35,799,314 for fiscal year 2026
  - $35,799,314 for fiscal year 2027
- CPI-only inflation adjustment occurs which started in FY24
- These funds are not included in the base revenue amount for subsequent years

PDUFA Revenue Setting Process

20% of annual revenue amount divided by FAEs = application fee



- 20% / 80% is written into statute

FAE = full-application equivalent

An application requiring covered clinical data counts as one FAE. An application not requiring covered clinical data counts as one-half of an FAE. An application withdrawn before filing, or refused filing, counts as one-fourth of an FAE if the applicant had paid a full application fee, or one eighth of an FAE if the applicant had paid one-half of the full application fee amount.

Actual Amounts for FY23 and FY24 Fee-Setting

Component	FY23 Amounts	% Above FY23 Base Amount	FY24 Amounts	% Above FY24 Base Amount	Average Increase %
Base Amount	$ 1,151,522,958		$ 1,256,844,387		
Inflation Adjustment	$ 18,889,583	1.6%	$ 48,886,219	3.9%	2.8%
Strategic Hiring and Retention Adjustment	$ 9,000,000	0.8%	$ 4,000,000	0.3%	0.5%
Capacity Planning Adjustment	$ 11,658,153	1.0%	$ 23,936,069	1.9%	1.5%
Additional Dollar Amounts	$ 65,773,693	5.7%	$ 25,097,671	2.0%	3.9%
Operating Reserve Adjustment	$ 9,088,943	0.8%	$ -	0.0%	0.4%
Additional Direct Costs	$ 44,386,150	3.9%	$ 63,339,404	5.0%	4.4%
Total (rounded)	$ 1,310,319,000		$ 1,422,104,000		

Application Fee Total *(20% of total)*	$ 262,063,800		$ 284,420,800
Estimated Fee-Paying FAEs	80.83		70.25
Fee Amount	$ 3,242,026		$ 4,048,695

Negotiated enhancements are the largest contributor to the increase in revenue amounts

Component	FY23 Amounts	% Above FY23 Base Amount	FY24 Amounts	% Above FY24 Base Amount	Average Increase %
Base Amount	$ 1,151,522,958		$ 1,256,844,387		
Inflation Adjustment	$ 18,889,583	1.6%	$ 48,886,219	3.9%	2.8%
Strategic Hiring and Retention Adjustment	$ 9,000,000	0.8%	$ 4,000,000	0.3%	0.5%
Capacity Planning Adjustment	$ 11,658,153	1.0%	$ 23,936,069	1.9%	1.5%
Additional Dollar Amounts	$ 65,773,693	5.7%	$ 25,097,671	2.0%	3.9%
Operating Reserve Adjustment	$ 9,088,943	0.8%	$ -	0.0%	0.4%
Additional Direct Costs	$ 44,386,150	3.9%	$ 63,339,404	5.0%	4.4%
Total (rounded)	$ 1,310,319,000		$ 1,422,104,000		

Addition Dollar Amounts (for FTEs for PDUFA VII enhancements) and Additional Direct Costs (for operating expenses for PDUFA VII enhancements) are the largest contributors to the increase in the annual revenue amount

But the change in estimated fee-paying FAEs is the most significant factor driving the fee increase

Reduction in estimated fee-paying FAEs increased the fee by $530k

Component	FY23 Amounts	% Above FY23 Base Amount	FY24 Amounts	% Above FY24 Base Amount	Average Increase %
Base Amount	$ 1,151,522,958		$ 1,256,844,387		
Inflation Adjustment	$ 18,889,583	1.6%	$ 48,886,219	3.9%	2.8%
Strategic Hiring and Retention Adjustment	$ 9,000,000	0.8%	$ 4,000,000	0.3%	0.5%
Capacity Planning Adjustment	$ 11,658,153	1.0%	$ 23,936,069	1.9%	1.5%
Additional Dollar Amounts	$ 65,773,693	5.7%	$ 25,097,671	2.0%	3.9%
Operating Reserve Adjustment	$ 9,088,943	0.8%	$ -	0.0%	0.4%
Additional Direct Costs	$ 44,386,150	3.9%	$ 63,339,404	5.0%	4.4%
Total (rounded)	$ 1,310,319,000		$ 1,422,104,000		

Application Fee Total *(20% of total)*	$ 262,063,800		$ 284,420,800
Estimated Fee-Paying FAEs	80.83		70.25
Fee Amount	$ 3,242,026		$ 4,048,695

Estimated Fee-Paying FAEs		80.83
Fee Amount		$ 3,518,608
Difference due to FAE change ($)		$ 530,087
Difference due to FAE change (%)		15.1%

To demonstrate the impact of the FAE change on the FY24 fee amount, the estimated fee-paying FAE number from FY23 is used here.

If the fee-paying FAEs had remained constant, the fee would have been $3.5M instead of $4M

PDUFA VI experienced increases in application review workload while fewer applications paid fees

	PDUFA V						PDUFA VI					
Component	FY13	FY14	FY15	FY16	FY17	PDUFA V Average	FY18	FY19	FY20	FY21	FY22	PDUFA VI Average
Original Priority NMEs and BLAs	19	28	25	23	31	**25.2**	48	44	54	52	43	**48.2**
Original Standard NMEs and BLAs	35	21	32	24	22	**26.8**	22	35	29	29	33	**29.6**
Original Priority non-NMEs and BLAs	8	10	9	12	24	**12.6**	16	16	14	22	11	**15.8**
Original Standard non-NMEs and BLAs	76	72	84	72	81	**77**	69	68	59	72	44	**62.4**
Sum of NMEs and BLAs	54	49	57	47	53	**52.0**	70	79	83	81	76	**77.8**
Sum of Non-NMEs and BLAs	84	82	93	84	105	**89.6**	85	84	73	94	55	**78.2**
Sum of Original NDAs and BLAs	138	131	150	131	158	**141.6**	155	163	156	175	131	**156.0**
Fee-Paying FAEs		73.4	82.0	70.5	81.8	**76.9**	68.9	86.8	65.3	90.5	55.0	**73.3**
Proportion of Fee-Paying FAEs to Total NDAs and BLAs		56.0%	54.6%	53.8%	51.7%	**54.0%**	44.4%	53.2%	41.8%	51.7%	42.0%	**46.6%**

Sources:

PDUFA FY18 & FY23 Performance Reports
PDUFA Fee-Setting Federal Register Notices

PDUFA VI experienced increases in application review workload while fewer applications paid fees

	PDUFA V						PDUFA VI					
Component	FY13	FY14	FY15	FY16	FY17	PDUFA V Average	FY18	FY19	FY20	FY21	FY22	PDUFA VI Average
Original Priority NMEs and BLAs	19	28	25	23	31	**25.2**	48	44	54	52	43	**48.2**
Original Standard NMEs and BLAs	35	21	32	24	22	**26.8**	22	35	29	29	33	**29.6**
Original Priority non-NMEs and BLAs	8	10	9	12	24	**12.6**	16	16	14	22	11	**15.8**
Original Standard non-NMEs and BLAs	76	72	84	72	81	**77**	69	68	59	72	44	**62.4**
Sum of NMEs and BLAs	54	49	57	47	53	**52.0**	70	79	83	81	76	**77.8**
Sum of Non-NMEs and BLAs	84	82	93	84	105	**89.6**	85	84	73	94	55	**78.2**
Sum of Original NDAs and BLAs	138	131	150	131	158	**141.6**	155	163	156	175	131	**156.0**
Fee-Paying FAEs		73.4	82.0	70.5	81.8	**76.9**	68.9	86.8	65.3	90.5	55.0	**73.3**
Proportion of Fee-Paying FAEs to Total NDAs and BLAs		56.0%	54.6%	53.8%	51.7%	**54.0%**	44.4%	53.2%	41.8%	51.7%	42.0%	**46.6%**

Sources:

PDUFA FY18 & FY23 Performance Reports
PDUFA Fee-Setting Federal Register Notices

Application review workload increased in PDUFA VI over PDUFA V:

- Average annual applications increased (141.6 to 156.0)
- Proportion of NMEs increased, driving more workload (52.0 to 77.8)

Fewer applications paid fees

- Fewer average annual fee-paying FAEs (76.9 to 73.3)
- Lower proportion of fee-paying FAEs to total NDAs & BLAs (54.0% to 46.6%)

PDUFA VI experienced increases in application review workload while fewer applications paid fees

	PDUFA V						PDUFA VI					
Component	FY13	FY14	FY15	FY16	FY17	PDUFA V Average	FY18	FY19	FY20	FY21	FY22	PDUFA VI Average
Original Priority NMEs and BLAs	19	28	25	23	31	**25.2**	48	44	54	52	43	**48.2**
Original Standard NMEs and BLAs	35	21	32	24	22	**26.8**	22	35	29	29	33	**29.6**
Original Priority non-NMEs and BLAs	8	10	9	12	24	**12.6**	16	16	14	22	11	**15.8**
Original Standard non-NMEs and BLAs	76	72	84	72	81	**77**	69	68	59	72	44	**62.4**
Sum of NMEs and BLAs	54	49	57	47	53	**52.0**	70	79	83	81	76	**77.8**
Sum of Non-NMEs and BLAs	84	82	93	84	105	**89.6**	85	84	73	94	55	**78.2**
Sum of Original NDAs and BLAs	138	131	150	131	158	**141.6**	155	163	156	175	131	**156.0**
Fee-Paying FAEs		73.4	82.0	70.5	81.8	**76.9**	68.9	86.8	65.3	90.5	55.0	**73.3**
Proportion of Fee-Paying FAEs to Total NDAs and BLAs		56.0%	54.6%	53.8%	51.7%	**54.0%**	44.4%	53.2%	41.8%	51.7%	42.0%	**46.6%**

Sources:

PDUFA FY18 & FY23 Performance Reports
PDUFA Fee-Setting Federal Register Notices

These last three years were used to estimate fee-paying FAEs for FY24.

This also coincides with an apparent increase in volatility around the COVID-19 pandemic years.

Similar dynamics apply to the PDUFA program fees & GDUFA; BsUFA has avoided this partly due to design and partly to industry growth

With a fixed percentage allocation of the target revenue to specific fee-types:

- Fees will likely go up if the denominator estimator is going down; fees will likely go down if the denominator estimator is going up

- This may result in disconnects where fee amounts could shift independently from the overall workload of the program

- BsUFA has been able to avoid this, in part through:
  - A floating percentage allocation of the target revenue to each fee type
  - Increases in the denominators associated with each fee type (351k BLAs, BPDs, approved products)

Summary

- Application fees do not pay for the review of specific applications. They contribute to the funding for the totality of the PDUFA program
- While workload has been increasing, fewer full application equivalents have been paying the fee
    - **Those that are paying the application fee must then pay a larger fee**
- To mitigate this impact, future PDUFAs may need more flexibility in fee-setting and/or more stable fee source(s)
- Fewer fee-paying FAEs does not mean less work; workload has been increasing due to more total submissions and more complex submissions
- Similar dynamics could apply to other programs under certain conditions

10:20 – 10:30 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

Resource Capacity Planning (RCP) Commitments in PDUFA VII, BsUFA III, and GDUFA III

- PDUFA VII[1], BsUFA III[2], and GDUFA III[3] include a set of commitments which continue to 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 RCP capability

- The implementation of these RCP commitments was detailed in the 2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan[4] that was published March 2023. Annual updates to this plan will be provided to articulate Agency progress towards the commitments made

- The first annual update was published in March 2024

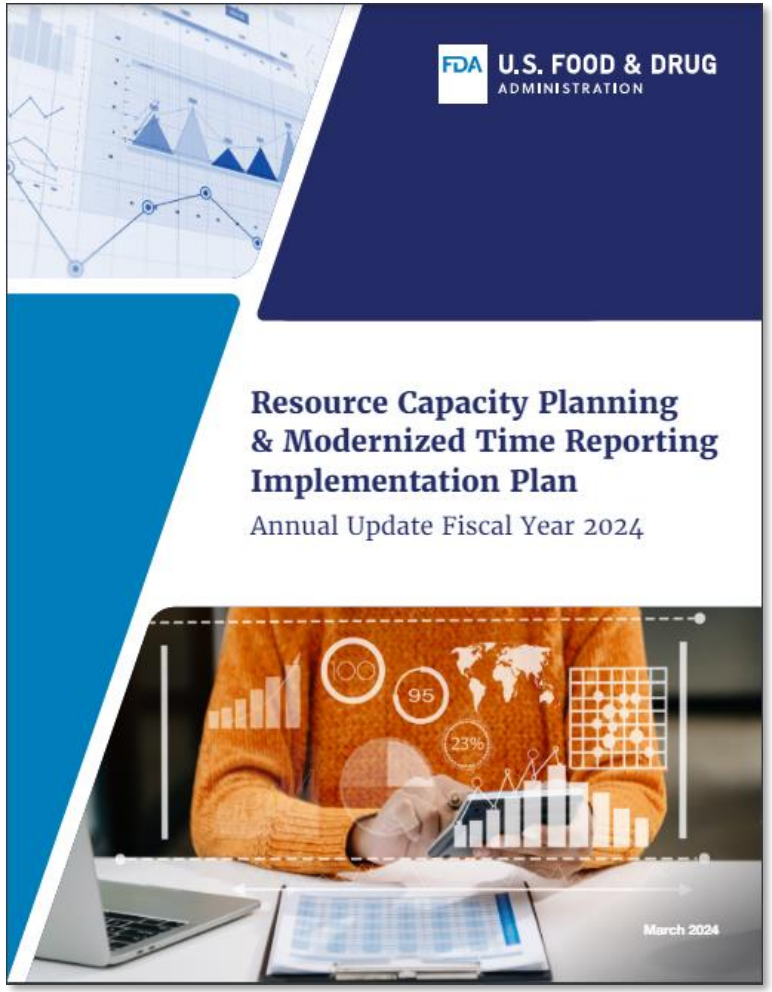
- The following slides will summarize the updates provided in the first annual update to the 2023 RCP Implementation Plan

[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
[4] 2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan

Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024

The Resource Capacity Planning & Modernized Time Reporting Implementation Plan: FY 2024 Annual Update[1] provided updates on progress made in the following areas:

1. Integrated Project Management, Portfolio Analytics, and Reporting Feasibility Assessment;
2. RCP Updated Concept of Operations;
3. Continual Improvement of Time Reporting;
4. Continual Improvement of the CPA;
5. Integrating RCP Analyses into Financial and Operational Decision-Making Processes; and
6. Implementation of the GDUFA CPA.

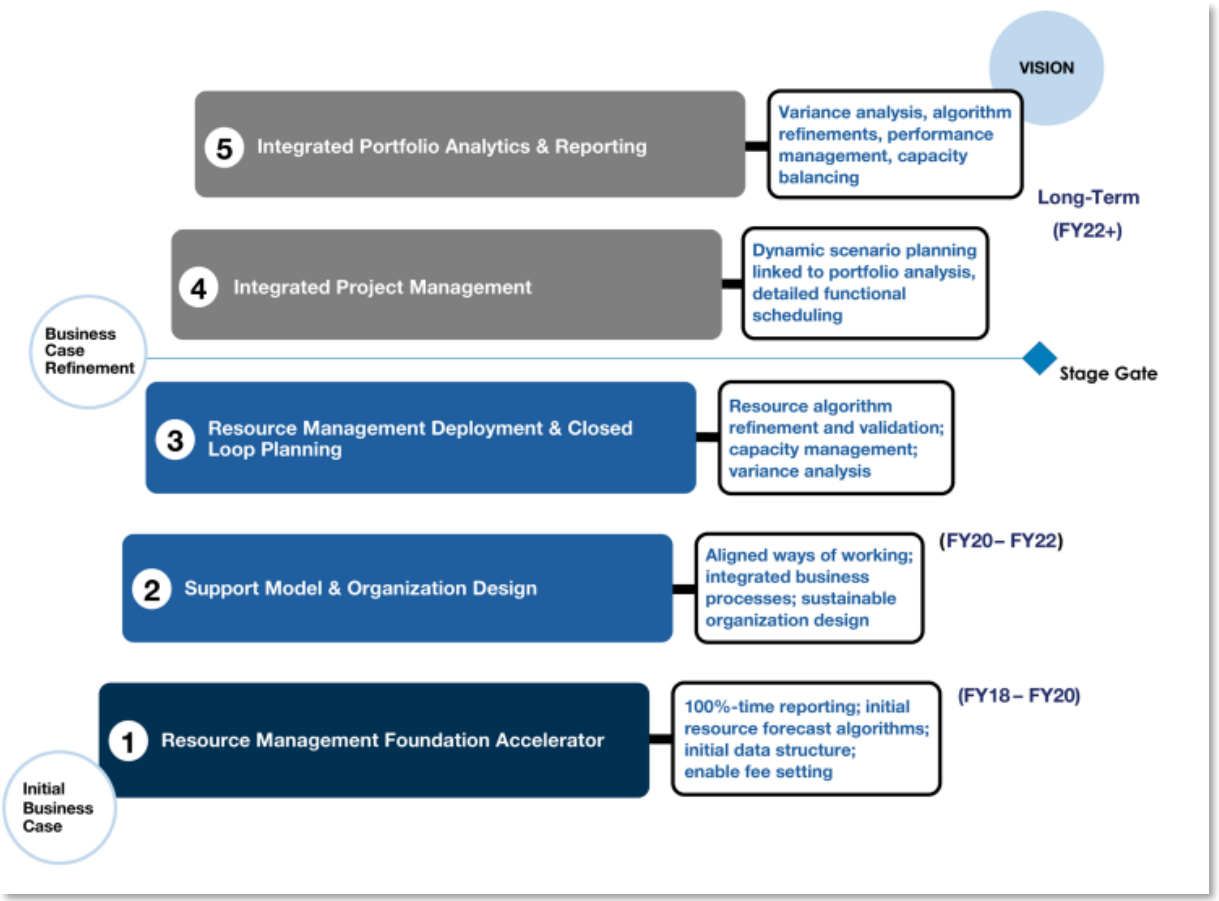


[1] Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024

1. Integrated Project Management, Portfolio Analytics, and Reporting Feasibility Assessment

- RCP at FDA came out of the previous authorization period (FY 2018 – FY 2022). A 2018 RCP Implementation Plan[1] was published and articulated five phases of RCP implementation
- The first three phases described in the 2018 RCP Implementation Plan have been largely implemented and are undergoing continual improvement
- For the current authorization period, **FDA has engaged a contractor to conduct a feasibility study of Phases 4-5 of the 2018 RCP Implementation Plan** which include integrated project management, portfolio analytics, and reporting
- This **feasibility assessment** is ongoing and expected to be **complete by the end of CY 2024**

RCP Implementation Phases from the 2018 RCP Implementation Plan



[1] 2018 Resource Capacity Planning & Modernized Time Reporting Implementation Plan

Reference:

2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.1, page 15

Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.1, page 4

2. RCP Updated Concept of Operations

Building on the RCP foundation developed during the previous authorization (FY 2018 – FY 2022), FDA is now focusing on sustaining, refining, and expanding the RCP capability:

- FDA is currently engaged in an effort to refine the existing RCP support and operating model. This will be reviewed and adapted annually as part of a continual improvement process
- Concurrently, refinements to the operating model for the Insight Time Reporting (ITR) program are being explored as it continues to be implemented throughout the Agency
    - The Insight System Oversight Board, a cross-Center board has been established to more closely coordinate ITR-related priorities across the Agency

Reference:
2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.2, page 15
Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.2, page 4

3. Continual Improvement of Time Reporting

- In September 2023, **the Center for Biologics Evaluation and Research (CBER)** successfully transitioned its full-time reporting capability to the Insight Time Reporting (ITR) system. ITR offers improved functionality and new features to support CBER's continuing efforts to improve its time reporting

- In FY 2023, **the Center for Drug Evaluation and Research (CDER)** institutionalized an annual review process under its ITR Change Control Board to review opportunities to remove time reporting codes that are no longer needed, thus minimizing time reporting burden and ensure categories remain relevant

- In April 2023, **the Office of Regulatory Affairs (ORA)** celebrated the one-year anniversary of the full implementation of ITR to all offices. Throughout the past year, ORA has pursued several initiatives to improve compliance and expand data accessibility. As the program reaches maturity, ORA will continue to use a data-driven approach to make improvements to the code, guidance, and procedures to ensure ORA fully realizes the potential of ITR

Insight Time Reporting

Reference:
2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.3, page 15-16
Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.3, page 4-5

4. Continual Improvement of the CPA

Enhancements and continual improvements of the CPA and related process have continued in technical, analytical, process, and statutory areas:

- **Technical and analytical improvements include:**
  - Continued efforts toward establishing a cloud-based technology platform to support RCP in CDER and CBER
  - Improvements have continued for all constituent analytical aspects of the CPAs, including all submission forecast models
- **Process improvements include**:
  - Advances in automating and formalizing incorporation of an annual variance analysis process across the CPAs to create efficiency and to identify opportunities for continued enhancements
- **Enhancements related to statutory areas:**
  - PDUFA VII expanded the definition of the PDUFA program to include certain allergenics products. These products were incorporated into the CPA models used in FY 2024 fee-setting
  - Annual reports, post-marketing commitments/post-marketing requirements (PMR/PMCs), and active Risk Evaluation and Mitigation Strategies (REMs) were also incorporated into the CPAs, as relevant, for FY 2024 fee-setting

Reference:
2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.4, page 16
Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.4, page 5-6

5. Integrating RCP Analyses into Financial and Operational Decision-Making Processes

RCP work products are well-integrated into financial processes and work continues to adapt approaches to support constituent offices in CDER and CBER, including:

- Establishing fit-for-purpose models to meet the needs of offices
- Model development efforts for internal uses are currently underway alongside an organizational needs assessment to help target opportunities moving forward

Reference:
2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.5, page 17
Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.5, page 6

6. The Implementation of the GDUFA CPA

The GDUFA CPA was implemented for CDER for FY 2024 fee-setting[1]

- CDER is now focused on continual improvements, including:
  - Evaluating readiness to enable the distinction of complex original ANDAs from non-complex original ANDAs, as well as Prior Approval Supplements from Changes-Being-Effected supplements. These potential enhancements would not be implemented before FY 2026 fee-setting
  - Engaging in the standard continual improvement process including annual variance analysis and identification of any opportunities for continued enhancements
- ORA is aiming for implementation of its portion of the GDUFA CPA for FY 2026 fee-setting to ensure readiness of its data and methodology

[1] Federal Register Notice: Generic Drug User Fee Rates for Fiscal Year 2024
Reference:
2023 Resource Capacity Planning and Modernized Time Reporting Implementation Plan, Section 3.2.6, page 17-18
Resource Capacity Planning & Modernized Time Reporting Implementation Plan: Annual Update Fiscal Year 2024, Section 3.2.6, page 6

10:30 – 10:40 AM

Wrap Up and Additional Information

Kichelle Joseph
Acting 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 6, 2024, 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**:**

- 2024 Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments - 06/06/2024 | FDA