

User Fee Financial Management and the 5-Year Financial Plans

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- Enhancing Financial Management
 - FDA has taken steps to become more efficient and transparent
- Purpose and Background – 5-Year Financial Plans
- Planning Process
 - Organizations within FDA
 - Governance and Coordination
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- Overview of the Financial Plans
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 - Obligations
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Enhancing Financial Management

- Resource Capacity Planning and Modernized Time Reporting
 - Published plan in March
 - <https://www.fda.gov/forindustry/userfees/ucm601909.htm>
- User Fee Five-Year Financial Plans
 - Published plans in March
 - <https://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/UserFeeFiveYearFinancialPlans/default.htm>
- Independent Financial Management Study
 - Contract awarded and evaluation underway
 - Planning to publish report during 2nd quarter FY 2019
 - Planning to discuss report at the UFA finance public meeting during 3rd quarter FY 2019
- Yearly Public Meetings

Purpose and Background – 5-Year Financial Plans

- The purpose of the Five-Year Financial Plan is to communicate the anticipated financial position of the user fee programs over the current five-year authorization period, and to communicate how FDA plans to utilize user fee resources to execute the program commitments and build the review program.
- To enhance financial transparency, FDA committed to publishing its Five-Year Financial Plan for BsUFA and GDUFA
 - This will include the publishing of yearly updates to the plans

Planning Process

- Organizations within FDA involved in the biosimilar and generic drug programs

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	Helps to ensure the safety, purity, and potency of biological products, including vaccines, blood and blood products, and gene therapies for the prevention, treatment, or cure of human diseases or conditions.
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.

Planning Process cont.

- Governance and Coordination
 - Robust user fee governance structure
 - Coordination within FDA is critical to our success

Planning Process cont.

- Program Goals
 - Funding decisions are driven primarily by FDA's mission and negotiated commitments

Overview of the BsUFA Financial Plan

- Biosimilar program collection estimates for FY 2018 through FY 2022

Target Revenue	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Actual	Estimate	Estimate	Estimate	Estimate
Base Amount	\$45,000,000	\$40,214,000	\$41,012,000	\$41,826,000	\$42,656,000
Inflation Adjustment	\$ -	\$798,000	\$814,000	\$830,000	\$847,000
Capacity Planning Adjustment	N/A	N/A	N/A	TBD	TBD
Operating Reserve Adjustment	N/A	TBD	TBD	TBD	TBD
FY 2018 Adjustment	(\$4,786,000)	N/A	N/A	N/A	N/A
Target Revenue Total	\$40,214,000	\$41,012,000	\$41,826,000	\$42,656,000	\$43,503,000

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.
- The capacity planning adjustment is intended to adjust the BsUFA target revenue for changes in the workload, or capacity needs of the program. The method will be established through a process outlined in statute. This will include a third-party assessment of methodological options to be published for public comment.
- The operating reserve adjustment was established in statute to provide a mechanism to support the management of a reasonable amount of fee funds carried over from year to year. FDA has committed to keeping the carryover balance below 21 weeks of operating by FY22.

Overview of the BsUFA Financial Plan

- Biosimilar obligation details

User Fee Obligations	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Cash Available for Obligation	\$88,437,308	\$88,984,011	\$84,336,052	\$76,519,487	\$69,038,929
Payroll & Operating					
CBER	\$208,018	\$458,612	\$716,717	\$723,983	\$731,324
CDER	\$31,055,273	\$36,720,837	\$40,875,344	\$41,289,779	\$41,708,416
ORA	\$1,382,041	\$1,396,054	\$1,410,208	\$1,424,506	\$1,438,949
HQ	\$2,544,981	\$2,570,722	\$2,089,285	\$2,110,468	\$2,131,866
Total Rent	\$1,505,875	\$1,520,934	\$1,536,143	\$1,551,504	\$1,567,019
Total FDA Central	\$1,986,384	\$2,006,248	\$2,026,310	\$2,046,573	\$2,067,039
Total Shared Services	\$1,782,726	\$1,800,553	\$1,818,559	\$1,836,744	\$1,855,112
Total Obligations	\$40,465,297	\$46,473,959	\$50,472,565	\$50,983,558	\$51,499,725

Overview of the BsUFA Financial Plan

- Biosimilar Carryover details

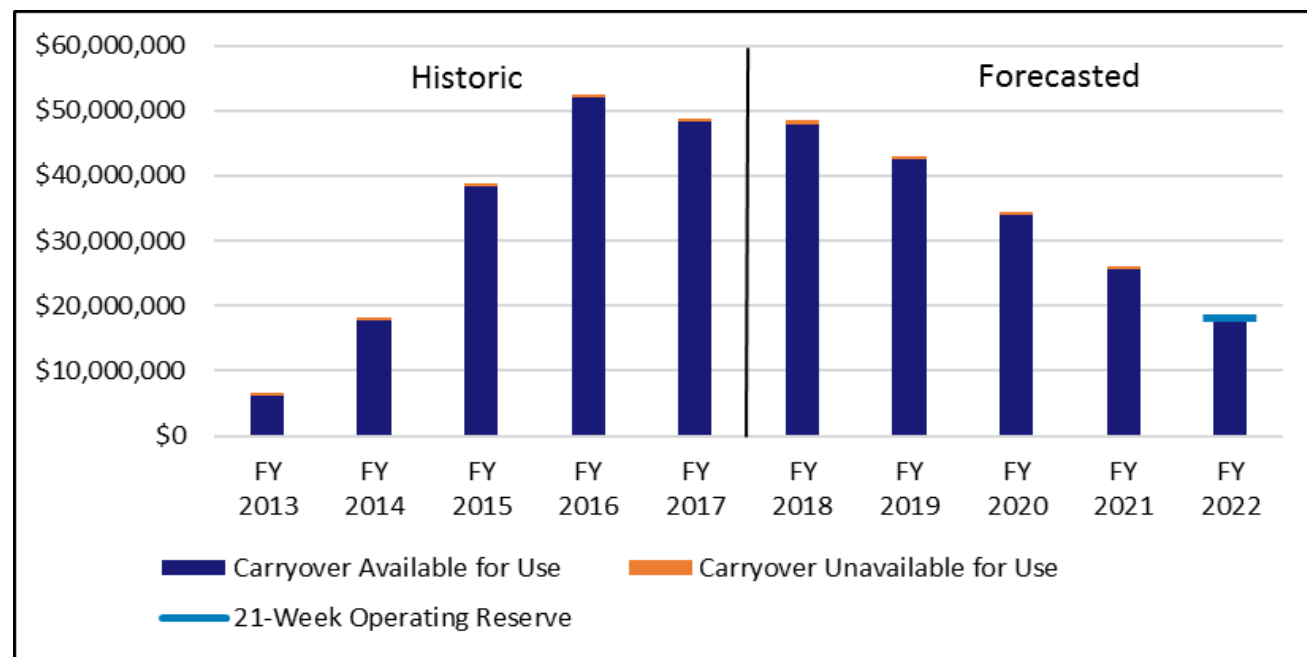
Budgetary Resources	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	\$40,214,000[†]	\$41,012,000	\$41,826,000	\$42,656,000	\$43,503,000
Cash Collections	\$40,214,000	\$41,012,000	\$41,826,000	\$42,656,000	\$43,503,000
Carryover Available for Use, Beginning of Year	\$48,223,308 [†]	\$47,972,011	\$42,510,052	\$33,863,487	\$25,535,929
Total Cash Available for Obligation	\$88,437,308	\$88,984,011	\$84,336,052	\$76,519,487	\$69,038,929

Obligations	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Payroll & Operating	\$35,190,312	\$41,146,224	\$45,091,553	\$45,548,736	\$46,010,555
Total Rent	\$1,505,875	\$1,520,934	\$1,536,143	\$1,551,504	\$1,567,019
Total FDA Central	\$1,986,384	\$2,006,248	\$2,026,310	\$2,046,573	\$2,067,039
Total Shared Services	\$1,782,726	\$1,800,553	\$1,818,559	\$1,836,744	\$1,855,112
Total Obligations	\$40,465,297	\$46,473,959	\$50,472,565	\$50,983,558	\$51,499,725

Carryover	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	\$48,472,011	\$43,010,052	\$34,363,487	\$26,035,929	\$18,039,204
Carryover Unavailable for Use, End of Year	(\$500,000)	(\$500,000)	(\$500,000)	(\$500,000)	(\$500,000)
Carryover Available for Use, End of Year	\$47,972,011	\$42,510,052	\$33,863,487	\$25,535,929	\$17,539,204

Overview of the BsUFA Financial Plan

- Biosimilar Carryover details cont.
 - Historic and Forecasted Carryover Available by Fiscal Year



Overview of the GDUFA Financial Plan

- Generic drug program collection estimates for FY 2018 through FY 2022

Target Revenue	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Actual	Estimate	Estimate	Estimate	Estimate
Base Amount	\$493,600,000	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000
Inflation Adjustment	\$ -	\$9,799,000	\$9,994,000	\$10,192,000	\$10,395,000
Target Revenue Total	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000

- Base amount is set in statute
- The inflation adjustment adjusts the base amount to maintain the purchasing power of fee funds in consideration of inflation.

Overview of the GDUFA Financial Plan

- Generic drug obligation details

User Fee Obligations	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Cash Available for Obligation	\$631,012,048	\$652,632,425	\$643,354,387	\$640,738,168	\$640,122,521
Payroll & Operating					
CBER	\$966,443	\$982,409	\$999,005	\$1,015,892	\$1,033,075
CDER	\$317,087,240	\$355,752,990	\$361,762,904	\$367,878,059	\$374,100,347
ORA	\$47,066,994	\$47,844,559	\$48,652,821	\$49,475,237	\$50,312,061
HQ	\$45,610,178	\$46,332,834	\$42,310,661	\$43,025,871	\$43,753,610
Total Rent	\$25,539,705	\$25,795,102	\$26,053,053	\$26,313,583	\$26,576,719
Total FDA Central	\$19,837,301	\$20,035,674	\$20,236,031	\$20,438,391	\$20,642,775
Total Shared Services	\$25,670,762	\$25,927,470	\$26,186,744	\$26,448,612	\$26,713,098
Total Obligations	\$481,778,623	\$522,671,038	\$526,201,220	\$534,595,646	\$543,131,686

Overview of the GDUFA Financial Plan

- Generic drug carryover details

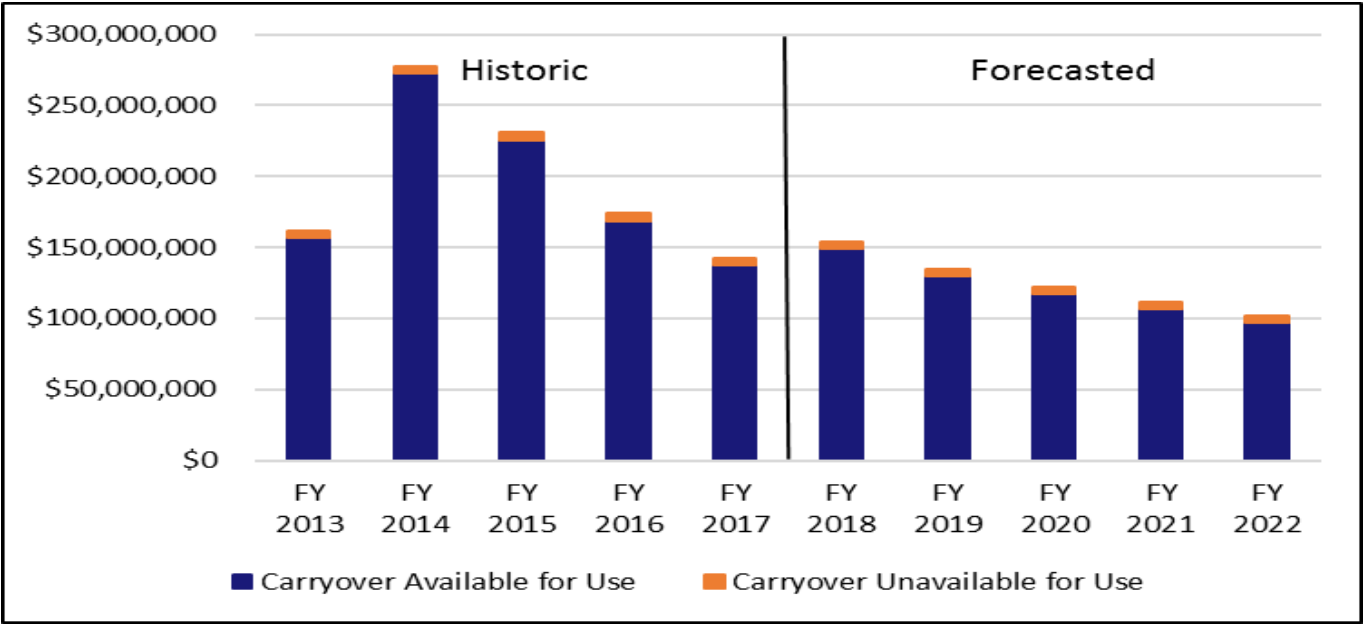
Budgetary Resources	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Target Revenue	\$493,600,000 [†]	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000
Cash Collections	\$493,600,000	\$503,399,000	\$513,393,000	\$523,585,000	\$533,980,000
Carryover Available for Use, Beginning of Year	\$137,412,048 [†]	\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521
Total Cash Available for Obligation	\$631,012,048	\$652,632,425	\$643,354,387	\$640,738,168	\$640,122,521

Obligations	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Payroll and Operating	\$410,730,855	\$450,912,792	\$453,725,391	\$461,395,060	\$469,199,094
Total Rent	\$25,539,705	\$25,795,102	\$26,053,053	\$26,313,583	\$26,576,719
Total FDA Central	\$19,837,301	\$20,035,674	\$20,236,031	\$20,438,391	\$20,642,775
Total Shared Services	\$25,670,762	\$25,927,470	\$26,186,744	\$26,448,612	\$26,713,098
Total Obligations	\$481,778,623	\$522,671,038	\$526,201,220	\$534,595,646	\$543,131,686

Carryover	FY 2018	FY 2019	FY 2020	FY 2021	FY 2022
	Estimate	Estimate	Estimate	Estimate	Estimate
Total Carryover, End of Year	\$154,233,425	\$134,961,387	\$122,153,168	\$111,142,521	\$101,990,835
Carryover Unavailable for Use, End of Year	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)	(\$5,000,000)
Carryover Available for Use, End of Year	\$149,233,425	\$129,961,387	\$117,153,168	\$106,142,521	\$96,990,835

Overview of the GDUFA Financial Plan

- Generic drug carryover details cont.
 - Historic and Forecasted Carryover Available by Fiscal Year





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