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

June 23, 2026
1:00 PM – 2:30 PM

Agenda

Topic	Presenter	Time
Begin Meeting	**Kichelle Joseph** Director, Immediate Office Office of Finance, Budget, and Acquisitions	1:00 – 1:05 PM
Welcome and Introduction	**Benjamin Moncarz** Chief Financial Officer Office of Finance, Budget, and Acquisitions	1:03 – 1:08 PM
Update on 5-Year Financial Plans	**Joshua Kirk** Financial Analyst Office of Finance, Budget, and Acquisitions	1:08 – 1:38 PM
Resource Capacity Planning Update	**Josh Barton** Office of Finance, Budget, and Acquisitions	1:38 – 1:48 PM
Wrap Up & Additional Information	**Kichelle Joseph** Director, Immediate Office Office of Finance, Budget, and Acquisitions	1:48– 1:53 PM
	Total Time	**65 minutes**

Welcome and Introduction

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

Update on 5-Year Financial Plans

Joshua Kirk
Financial Analyst
Office of Finance, Budget, and Acquisitions

Overview of the PDUFA Financial Plan

Budgetary Resources	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Target Revenue	**$1,310,319,000**	**$1,422,104,000**	**$1,478,740,000**	**$1,478,740,000**	**$1,556,038,000**	**$1,633,772,000**
Total Carryover, Beginning of Year	$287,669,825	$275,515,520	$297,371,048	$297,371,048	$413,940,928	$601,269,985
Net Collections	$1,222,888,088	$1,381,243,203	$1,464,056,921	$1,457,945,602	$1,556,038,000	$1,633,772,000
Recoveries	$16,400,359	$17,785,244	$15,847,000	$18,301,186	$17,496,000	$17,496,000
Total Budgetary Resources	**$1,526,958,272**	**$1,674,543,967**	**$1,777,274,969**	**$1,773,617,836**	**$1,987,474,928**	**$2,252,537,985**

User Fee Obligations	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Payroll	**$813,591,182**	**$918,155,812**	**$966,967,735**	**$971,766,208**	**$910,030,649**	**$981,086,117**
CBER	$135,448,033	$159,563,624	$186,755,561	$185,178,088	$174,242,674	$190,092,588
CDER	$626,848,682	$711,497,874	$736,875,971	$740,906,189	$699,140,462	$752,914,836
CDRH	$2,646,738	$3,058,788	$2,321,151	$3,327,963	$2,097,367	$2,196,384
OII	$6,898,327	$7,653,639	$6,827,890	$7,682,014	$8,285,121	$8,676,262
HQ	$41,749,402	$36,381,887	$34,187,162	$34,671,954	$26,265,025	$27,206,047
Operating	**$238,169,945**	**$253,766,997**	**$227,668,663**	**$167,917,959**	**$229,931,374**	**$245,680,829**
CBER	$60,103,396	$73,196,127	$56,315,484	$42,164,463	$48,918,147	$59,225,500
CDER	$155,786,743	$160,904,091	$152,223,862	$106,538,311	$158,782,336	$164,267,292
CDRH	$1,058	$0	$1,339,733	$0	$116,846	$123,626
OII	$1,192,391	$1,419,359	$2,212,849	$1,187,684	$1,138,294	$1,194,864
HQ	$21,086,357	$18,247,420	$15,576,735	$18,027,501	$20,975,751	$20,869,547
Total Rent	**$48,137,237**	**$28,672,907**	**$31,793,381**	**$28,103,457**	**$34,053,116**	**$36,468,304**
Total Shared Services	**$151,544,388**	**$176,577,203**	**$172,371,010**	**$191,889,284**	**$212,189,804**	**$221,997,557**
Total Obligations	**$1,251,442,752**	**$1,377,172,919**	**$1,398,800,789**	**$1,359,676,908**	**$1,386,204,943**	**$1,485,232,807**

Carryover	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Total Carryover, End of Year	**$275,515,520**	**$297,371,048**	**$378,474,180**	**$413,940,928**	**$601,269,985**	**$767,305,178**
Unappropriated Amounts	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)	($78,850,995)
Total Available Carryover, End of Year	**$196,664,525**	**$218,520,053**	**$299,623,185**	**$335,089,933**	**$522,418,990**	**$688,454,183**
Future Year Refunds Allowance, Set Aside	($20,000,000)	($25,229,000)	($29,781,000)	($29,781,000)	($26,545,000)	($26,545,000)
Carryover Net of Unavailable and Set Aside, End of Year	**$176,664,525**	**$193,291,053**	**$269,842,185**	**$305,308,933**	**$495,873,990**	**$661,909,183**

Overview of the BsUFA Financial Plan

Budgetary Resources	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Target Revenue	**$41,600,000**	**$31,019,000**	**$56,012,000**	**$56,012,000**	**$55,841,000**	**$61,769,000**
Total Carryover, Beginning of Year	$43,317,275	$40,994,759	$22,056,573	$22,056,573	$29,098,392	$34,332,266
Net Collections	$59,629,003	$34,375,378	$56,012,000	$57,838,759	$55,841,000	$61,769,000
Recoveries	$1,014,458	$2,490,062	$1,279,000	$486,242	$1,330,000	$1,330,000
Total Budgetary Resources	**$103,960,736**	**$77,860,199**	**$79,347,573**	**$80,381,574**	**$86,269,392**	**$97,431,266**

User Fee Obligations	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Payroll	**$30,995,692**	**$32,806,350**	**$33,639,292**	**$34,879,223**	**$30,312,140**	**$32,394,773**
CBER	$82,007	$0	$0	$0	$0	$0
CDER	$28,975,314	$30,956,807	$32,189,539	$33,400,430	$28,352,876	$30,392,434
OII	$1,033,630	$1,145,173	$962,794	$976,205	$417,404	$428,313
HQ	$904,741	$704,370	$486,959	$502,588	$1,541,860	$1,574,026
Operating	**$22,056,017**	**$17,526,637**	**$12,490,107**	**$9,323,981**	**$14,059,073**	**$15,180,758**
CBER	$0	$0	$131,116	$0	$133,545	$143,440
CDER	$21,034,646	$16,911,298	$11,835,600	$8,999,677	$13,391,292	$14,514,896
OII	$111,425	$377,472	$287,636	$273,757	$249,225	$268,551
HQ	$909,946	$237,867	$235,755	$50,547	$285,011	$253,871
Total Rent	**$1,079,676**	**$255,388**	**$283,181**	**$283,181**	**$295,634**	**$316,602**
Total Shared Services	**$8,834,592**	**$5,215,252**	**$6,051,811**	**$6,796,797**	**$7,270,279**	**$7,591,012**
Total Obligations	**$62,965,977**	**$55,803,627**	**$52,464,391**	**$51,283,182**	**$51,937,126**	**$55,483,145**

Carryover	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Total Carryover, End of Year	**$40,994,759**	**$22,056,573**	**$26,883,182**	**$29,098,392**	**$34,332,266**	**$41,948,121**
Future Year Refunds Allowance, Set Aside	($1,000,000)	($873,000)	($873,000)	($873,000)	($1,441,000)	($1,441,000)
Carryover Net of Set Aside, End of Year	**$39,994,759**	**$21,183,573**	**$26,010,182**	**$28,225,392**	**$32,891,266**	**$40,507,121**

Overview of the GDUFA Financial Plan

Budgetary Resources	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Target Revenue	**$582,500,000**	**$613,538,000**	**$638,962,000**	**$638,962,000**	**$670,899,000**	**$702,146,000**
Total Carryover, Beginning of Year	$131,211,761	$120,195,906	$89,171,694	$89,171,695	$140,512,273	$209,423,308
Net Collections	$551,653,777	$569,359,591	$607,806,205	$620,713,654	$670,899,000	$702,146,000
Recoveries	$7,656,327	$12,580,852	$8,790,000	$8,683,062	$9,640,000	$9,640,000
Total Budgetary Resources	**$690,521,865**	**$702,136,348**	**$705,767,899**	**$718,568,411**	**$821,051,273**	**$921,209,308**

User Fee Obligations	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Payroll	**$359,048,484**	**$410,239,316**	**$388,090,916**	**$401,000,224**	**$401,529,461**	**$449,856,672**
CBER	$248,671	$0	$0	$0	$0	$0
CDER	$295,747,308	$340,158,030	$335,351,285	$345,359,305	$332,315,953	$374,946,841
OII	$40,357,466	$50,904,789	$35,217,057	$39,322,464	$51,350,810	$53,742,474
HQ	$22,695,039	$19,176,497	$17,522,574	$16,318,455	$17,862,698	$21,167,357
Operating	**$113,234,967**	**$110,217,838**	**$104,925,737**	**$84,099,487**	**$103,633,653**	**$105,980,112**
CBER	$0	$0	$292,624	$88	$92	$96
CDER	$93,006,393	$92,558,409	$84,969,217	$64,547,687	$76,680,967	$83,645,135
OII	$8,704,461	$7,791,673	$11,922,467	$6,518,140	$5,703,241	$6,406,610
HQ	$11,524,113	$9,867,756	$7,741,429	$13,033,572	$21,249,353	$15,928,271
Total Rent	**$15,134,245**	**$9,430,213**	**$10,456,504**	**$9,680,487**	**$11,533,680**	**$12,351,697**
Total Shared Services	**$82,908,264**	**$83,077,287**	**$75,865,018**	**$83,275,940**	**$94,931,171**	**$99,190,565**
Total Obligations	**$570,325,960**	**$612,964,654**	**$579,338,175**	**$578,056,138**	**$611,627,965**	**$667,379,046**

Carryover	FY 2023	FY 2024	FY 2025		FY 2026	FY 2027
	Actual	Actual	Estimate	Actual	Estimate	Estimate
Total Carryover, End of Year	**$120,195,906**	**$89,171,694**	**$126,429,724**	**$140,512,273**	**$209,423,308**	**$253,830,262**
Future Year Refunds Allowance, Set Aside	($4,000,000)	($4,000,000)	($6,002,000)	($6,002,000)	($5,604,000)	($5,604,000)
Carryover Net of Set Aside, End of Year	**$116,195,906**	**$85,171,694**	**$120,427,724**	**$134,510,273**	**$203,819,308**	**$248,226,262**

Resource Capacity Planning Update

Josh Barton
Office of Finance, Budget, and Acquisitions

Resource Capacity Planning Update

- Capacity planning efforts have been largely focused on consolidating and sustaining operations over the past year
  - Focus has included technical updates to strengthen the analytical platform
  - Updates to highlight include distinct models for complex and non-complex ANDAs
- The capacity planning adjustments (CPAs) for PDUFA, BsUFA, and GDUFA remain a key tool for ensuring appropriate staffing to address industry-submitted review workload
- The CPAs, however, are not expected to adjust the target revenue for these programs until the review functions have been restaffed

Wrap Up and Additional Information

Kichelle Joseph
Director, Immediate Office
Office of Finance, Budget, and Acquisitions

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-2026-N-3273 to locate this meeting
3. Submit your comment

You will have until **July 23, 2026, 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:

- Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments - 06/23/2026 | FDA

Thank You!