Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

February 19, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To provide substantive responses to Industry questions on the Fiscal Year (FY) 2025 PDUFA Financial Report to Congress and to relay FDA's thinking on Industry's ideas for the enterprise performance adjustment (EPA), capacity planning adjustment (CPA), and inflation adjustment.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Steve Berman	BIO
Angela Granum	CDER	Carl Garner	PhRMA (Eli Lilly)
Kate Greenwood	OCC	Kelly Goldberg	PhRMA
Kristopher Hoover	CDER	Kristy Lupejkis	PhRMA
Rebecca Kemp	CBER	Alison Maloney	PhRMA (Bayer)
Andrew Kish	CDER		
Eric Stone	CDER		

MEETING SUMMARY

FDA responded to Industry questions on data provided in the FY 2025 PDUFA Financial Report to Congress. FDA and Industry discussed components of the potential financial framework package, including the EPA, CPA, and inflation adjustment.

Discuss PDUFA FY 2025 Financial Report

Industry requested additional context around the increase in PDUFA payroll from fiscal year (FY) 2024 to FY 2025 as denoted in table 6 of the FY 2025 PDUFA Financial Report to Congress[1]. FDA stated the increase was due to lump sum leave payouts, severance payments to eligible staff who performed PDUFA-covered work and were separated due to the Reduction-in-Force, hiring in 2024 and early 2025, and a larger than average pay raise in 2024 (5.2%

[1] The FY 2025 PDUFA Financial Report can be found at https://www.fda.gov/media/190768/download?attachment

combined base and locality, representing the largest increase since 1980). FDA indicated that while lump sum leave payouts were completed in FY 2025, FY 2026 payroll may still show higher than expected values due to some separated staff receiving biweekly severance payments until July 2026, depending on length of service.

Industry also inquired about the increase in total process full-time equivalents (FTEs) from FY 2024 to FY 2025 in table 12 of the report. FDA stated these figures included employees on administrative leave and that the Agency would expect the total process FTEs to decrease over the next two FYs. FDA also noted the Agency had an increase in hiring through FY 2024 and the first quarter of FY 2025, which contributed to higher year-over-year FTE levels. In response to a question about the increase in the "HQ" line item, FDA shared that field lab staff from the Office of Inspections and Investigations were reorganized to the Office of the Chief Scientist, which falls under headquarters. FDA indicated that the next iteration of the PDUFA Financial Report will likely denote large shifts in process FTEs due to consolidation of Center functions into the Shared Services organization. FDA highlighted that the numbers displayed in the total process table do not represent headcount, but rather, FTE burn, a measurement of paid hours in a given FY. Industry expressed that FDA's answers to its questions were unanticipated and would require further discussion.

Address Industry Questions

The subgroup then revisited questions raised by Industry in the prior meeting. In response to whether the Agency would be open to having a public docket to receive public comment on the third-party study as part of the enterprise performance adjustment (EPA), FDA stated it would support having a mechanism in place for public stakeholders to have an opportunity to view the report and provide comment and perspective.

FDA also addressed Industry's proposal around the capacity planning adjustment (CPA) and EPA. In a scenario where FDA has fully restaffed to targeted payroll levels, and the third-party study recommends a downward adjustment, yet FDA decides to not take that adjustment, Industry proposed that FDA withhold the CPA for one year. FDA asked clarifying questions about Industry's proposal and explained that the CPA is forward looking and used to forecast future workload. FDA expressed that it did not support Industry's proposal, given FDA cannot predict the workload of the program in FY 2030 at the present. FDA stated it would be open to reflecting on how to ensure the adjustments in the financial framework are working together effectively.

Industry indicated they would need time to debrief the information relayed in the meeting around the FY 2025 Financial Report and that user fee funds had been expended towards severance and other related payments. Industry also stated its need to ensure the target payroll in the financial framework is reflective of FDA's true target payroll, including hiring in FY 2024 and the first quarter of FY 2025 and obligations related to severance.

Industry made an additional request around the inflation adjustment, proposing that FDA apply the inflation adjustment to the base revenue after adjustments have been made (e.g., EPA), as opposed to applying inflation to the base before that calculation. FDA said it would need time to assess the impact of this proposal.

Wrap-Up and Next Steps

The goals for the next meeting on February 24th are to review the PDUFA VIII ledger and to address any Industry questions on the information discussed in this meeting.