Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

March 10, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To hear Industry's perspective on FDA's counterproposal, to provide FDA's response on the public meeting commitment, and to discuss topics including other direct costs, the operating reserve tracking, reserving, reporting (OR TRR) calculations, and reporting details.

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
Christine Hunt	OCC	Alison Maloney	PhRMA (Bayer)
Rebecca Kemp	CBER	Drew Sansone	BIO (Alkermes)
Joshua Kirk	OO/OFBA		
Andrew Kish	CDER		

MEETING SUMMARY

Industry indicated they can agree to FDA's counterproposal on the capacity planning adjustment. Industry can also agree to the 10-12-week operating reserve range. FDA proposed to discontinue the public financial meeting commitment in PDUFA VIII to accommodate the technical meetings, accompanied by publicly available minutes, requested by Industry. The subgroup discussed other direct costs that will need to be included in the ledger. FDA presented a process for calculating the OR TRR. Industry and FDA considered what additional reporting information would contribute to the subgroup's transparency goals.

Industry's Response to FDA Counterproposal

Industry noted they had reflected on the previous meeting's discussion and the finance subgroup's progress around the inflation adjustment, the language around the OR TRR

specifically dedicated to hiring and retaining human drug review staff, and the enhanced reporting on payroll and obligations. Industry highlighted two outstanding items requiring their response: the operating reserve range and the capacity planning adjustment (CPA). Industry stated they would accept FDA's original proposal of a 10 – 12-week range for the operating reserve yet added that the implementation approach for that decreased range would need to be finalized. Industry acknowledged FDA's inability to agree to their proposal to maintain a CPA of zero for one year if the third-party assessment recommended an adjustment and FDA chose not to implement one. Industry accepted FDA's counterproposal to base the OR TRR on FY 2025 payroll.

FDA's Response on Public Meeting

Given FDA's prior agreement to offer a technical staff meeting each year after the fee-setting Federal Register Notice is published (see minutes from 3/5/26 for more information on technical staff meetings), and the workload associated with this effort, FDA proposed to discontinue the financial public meetings in PDUFA VIII, considering the amount of effort and relatively low turnout of external stakeholders. Industry emphasized transparency as the utmost priority and agreed with FDA's assertion that the technical staff meetings with published public meeting minutes could provide the same level of information as the public financial meetings.

Other Direct Costs

The subgroup acknowledged the pending discussion to be had on the costs of third-party assessments agreed to as part of the PDUFA VIII package, as well as the resource capacity planning (RCP) direct costs. FDA stated the Agency would reflect on the most appropriate way to estimate costs for a third-party study as part of the finance subgroup's enterprise performance adjustment (EPA). FDA noted the Agency had insourced the resource capacity planning capability and no longer required contract support. FDA indicated the time reporting licenses required across the Agency in support of RCP may benefit from being incorporated as a direct cost. The parties agreed to discuss the time reporting license costs as the commitment letter language is updated.

OR TRR Calculation Details

FDA presented a workflow for calculating the portion of the operating reserve that would be set-aside solely for payroll purposes to hire and retain staff for the human drug review program. Industry and FDA remarked upon several dependencies of the calculation, such as the updated baseline to FY 2025 payroll instead of FY 2024, as well as the application of actual inflation instead of assumed inflation. The subgroup also conferred on how to implement the OR TRR into statute.

Reporting Details

To begin the conversation on the enhanced reporting in the annual financial report that Industry would like to see, FDA noted the detailed accounting system the Agency is subject to in the Federal government, containing thousands of sub-object class codes. FDA then provided Table 2 published in the FY 2016 PDUFA Financial Report[1] that detailed FDA obligations to the object class code level, highlighting that this historical example was feasible for FDA to provide in PDUFA VIII. Industry and FDA discussed the overarching goal of the enhanced reporting: to provide transparency and demonstrate that payroll funds were being spent on FTEs utilized to support the human drug review program. FDA said it understood Industry's request and would consider how to re-envision the historical example to meet the needs Industry articulated.

Next Steps

The goal for the next meeting is for FDA and Industry to discuss the changes to statute proposed earlier in negotiations by FDA.

[1] The FY 2016 PDUFA Financial Report can be found at https://www.fda.gov/media/104263/download