



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

February 17, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To respond to Industry questions on the updated model presented in the previous meeting demonstrating the Operating Reserve Adjustment Tracking Reserving Reporting (ORA TRR) proposal with multiple staffing scenarios incorporating further details on Shared Services.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kate Greenwood	OCC
Kristopher Hoover	CDER
Rebecca Kemp	CBER
Andrew Kish	CDER

Industry

Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)

MEETING SUMMARY

Industry raised questions about the Fiscal Year (FY) 2025 PDUFA Financial Report to Congress for greater comprehension. Industry asked FDA to walk through the detailed ORA TRR model, then raised clarifying questions about the model and the potential financial framework package.

Industry Questions on ORA TRR Model and the Potential Financial Framework Package

Before addressing their questions on the ORA TRR model, given that the TRR model relies on reporting as a cornerstone feature, Industry raised questions about the FY 2025 PDUFA Financial Report to Congress, seeking to understand, in light of the reductions-in-force (RIFs) and significant voluntary departures FDA experienced in FY 2025, the reported increases in PDUFA payroll from FY 2024 to FY 2025. Industry also inquired about the increase in total

process full-time equivalents (FTEs) reported. FDA provided initial responses yet indicated more substantive explanations would be offered in the next meeting.

Industry requested FDA provide an overview of the mechanics of the ORA TRR model to ensure knowledge across all parties. FDA detailed how payroll funds would be captured in the operating reserve, then held in a special set-aside for reviewer staffing. FDA explained how it proposed to derive the relevant payroll figure (to compare against the baseline FY 2024 PDUFA payroll). Industry asked for confirmation that the set-aside reserve could only be spent on payroll, which FDA affirmed. The subgroup acknowledged that the reserved funding could be spent on payroll in the event of a shutdown in order to continue operations, but FDA clarified that once an appropriation was made to the Agency, the reserve would be replenished. FDA reiterated its preference for a payroll-based approach to measuring restaffing targets, indicating that such an approach would be much more feasible to plan, monitor, track, and interpret. FDA stated any PDUFA dollars not billed by Shared Services would count to the operating reserve.

The subgroup transitioned to the topic of the Enterprise Performance Adjustment (EPA). (For more information on the Enterprise Performance Adjustment, reference the 1/22/26 and 2/12/26 meeting minutes.) Industry asked how this adjustment mechanism would be reflected in an agreement. FDA indicated statutory language would be required to enable any change in the revenue amounts, while the Commitment Letter would likely detail parameters of the third-party study of efficiencies, workload, staffing, and other relevant factors. Industry asked if an explanation of any FDA decisions would be published. FDA noted that existing mechanisms, like the operating reserve adjustment, require FDA to provide a rationale for any decisions, so there is established precedent for this.

FDA and Industry discussed the merits of a titrated adjustment approach, if FDA were to choose to make an adjustment. Industry proposed that if FDA chose not to make an adjustment despite the third-party study recommending such, and FDA had met its restaffing payroll target, FDA should not make a Capacity Planning Adjustment (CPA) the following year. After asking clarifying questions, FDA stated they would consider Industry's proposal. Industry asked whether the third-party report would be published and made available for public comment: FDA responded that it would consider Industry's suggestion.

Industry expressed an interest in a cap on the inflation adjustment. FDA stated that the inflation adjustment is a lagging indicator representing cost increases that have already been experienced and that an inflation cap would therefore represent a cut to the program. As such, as previously noted, an inflation cap would require a detailed and lengthy discussion about which program features and goals would be impacted by an inflation adjustment cap. FDA reiterated that the EPA proposal is only being discussed with the understanding that there are no changes to the inflation adjustment being considered, which includes no consideration of a cap, and that there is alignment on a cap to the CPA.

Wrap-Up and Next Steps

The goals for the next meeting on February 19th are to provide further clarification on the FY 2025 PDUFA Financial Report to Congress and to address outstanding Industry questions on the potential financial framework package.