



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup

February 12, 2026 | 1:00pm-3:00pm

Virtual Format (Teams)

### MEETING PURPOSE

To review the updated PDUFA VIII financial ledger, present a detailed model demonstrating the Operating Reserve Adjustment Tracking, Reserving, and Reporting (ORA TRR) proposal with multiple staffing scenarios, and discuss outstanding revenue framework topics.

### PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Carl Garner	PhRMA (Eli Lilly)
Angela Granum	CDER	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis	PhRMA
Kristopher Hoover	CDER	Alison Maloney	PhRMA (Bayer)
Christine Hunt	OCC	Drew Sansone	BIO (Alkermes)
Rebecca Kemp	CBER		
Joshua Kirk	OO/OFBA		
Andrew Kish	CDER		
Stacy Yung	CDER		

### MEETING SUMMARY

FDA and Industry reviewed the updated PDUFA VIII ledger. FDA presented a detailed ORA TRR model incorporating Shared Services details per Industry request. The subgroup discussed enhanced Shared Services reporting through updates to the PDUFA Five-Year Financial Plan as well as the implementation of the Enterprise Performance Adjustment (EPA). FDA compiled a revenue framework package for Industry to consider.

### PDUFA VIII Ledger

FDA presented the updated financial ledger, which is intended to track the resource impacts of any negotiated agreements across subgroups. FDA and Industry discussed their understanding of the current slate of full-time equivalent (FTE) and direct cost figures captured in the ledger

with the shared understanding that resource impacts continue to be negotiated in parallel in other subgroups.

### **Review Updated Scenario Model**

FDA presented an updated Operating Reserve Adjustment Tracking, Reserving, and Reporting (ORA TRR) scenario model to facilitate greater understanding around how the mechanism would function in various hypothetical scenarios and how this approach will work in the context of fee setting. The updated model included an additional level of detail on the major obligations categories, i.e. Payroll, Shared Services, Operating, and Rent. FDA presented sample data to show how obligations may shift across these categories as Shared Services are consolidated. Industry inquired whether the reserve dollars set aside for reviewer staffing would ever result in FDA being below the operating reserve cap, necessitating an upward operating reserve adjustment. FDA explained that the special reserve set aside for reviewer staffing would be counted toward the available operating reserve and thus could not result in a change in the likelihood of an upward operating reserve adjustment being implemented in any given year.

Industry asked how unspent Shared Services funds, if any, would be handled. FDA explained that Shared Services costs are billed proportionally to programs based on consumption. If the Shared Services bills were less than expected, the difference could contribute to a higher operating reserve. These excess funds could also be reinvested in PDUFA payroll or used for PDUFA-allowable activities in Centers to support the human drug review program. Industry inquired what would happen in this model if FDA rapidly restaffed. FDA used the scenario model to demonstrate that the revenue framework under discussion would ensure that these financial resources are available for rapid restaffing; fully restaffing would essentially rebalance the collections and obligations, negating the need for downward operating reserve adjustments, assuming all other factors remain equal.

Industry asked further clarifying questions regarding the ORA TRR scenario model and the proposed revenue framework.

### **Revisit Other Topics**

FDA shared proposed commitment letter language for enhanced reporting in the PDUFA Five-Year Financial Plan on Shared Services. The subgroup discussed FDA's drafted language and planned reporting.

FDA then presented updates to its proposal for a new adjustment concept informed by an independent third-party study of efficiencies, staffing, and other relevant factors (see "Adjustment Discussion" topic from the 1/22/26 meeting). Now called the Enterprise Performance Adjustment (EPA), FDA indicated it would be open to an FDA option to revisit scheduled potential adjustments in FY 2031 and FY 2032, if circumstances warranted. Industry

requested clarification on how scheduled adjustments could be modified based on changing circumstances. FDA emphasized this adjustment process would be a managerial assessment and could be revisited if circumstances change. FDA explained this would provide flexibility to adjust the magnitude of reductions, if any, based on evolving conditions while maintaining the base revenue predictability. FDA stated the third-party study would only be performed once.

FDA reiterated that the inclusion of the EPA concept in the final negotiation package would require leaving the inflation adjustment unchanged with no cap and subgroup alignment on a capacity planning adjustment (CPA) cap. FDA reiterated the Agency's ongoing priority to standardize the CPA with other user fee programs. Specifically, FDA stated the Agency could align to a 3% cap on the PDUFA CPA in alignment with the Generic Drug User Fee Amendments (GDUFA) program. Industry noted their understanding that these elements (EPA, inflation adjustment, and CPA) were linked together as part of the overall package. FDA concluded by providing a comprehensive summary of the proposed revenue framework package. Industry acknowledged the substantial material provided would require further internal discussion before Industry is able to respond.

### **Wrap-Up and Next Steps**

The goals for the next meeting on February 17<sup>th</sup> are to address any Industry questions on the updated model presented by FDA.