



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

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

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To review updates to the PDUFA VIII financial ledger, to clarify workforce and full-time equivalent (FTE) numbers, and to provide further detail on the mechanics of the proposed operating reserve adjustment tracking, reserving, reporting (ORA TRR) approach.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CBER
Joshua Kirk	OO/OFBA
Andrew Kish	CDER
Stacy Yung	CDER

Industry

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

MEETING SUMMARY

FDA and Industry reviewed the PDUFA VIII financial ledger updates. FDA provided additional context on workforce and FTE numbers. FDA offered further granularity on the ORA TRR approach to clarify differing interpretations identified in the previous week's discussion.

PDUFA VIII Ledger

FDA presented updates to the ledger, which is intended to track the resource impacts of any agreements across subgroups. FDA and Industry discussed their respective understandings of resource agreements.

Workforce / FTE Numbers

FDA provided detailed explanations of workforce and FTE calculations to help illuminate the logic behind the hiring targets provided in the previous meeting. FDA explained the complexities around measuring PDUFA workload. FDA answered Industry's questions on payroll nomenclature.

ORA TRR Approach

FDA presented a detailed process for the ORA TRR approach. FDA suggested using a PDUFA payroll target provided in historical PDUFA financial reports as the baseline to compare against PDUFA payroll actuals in PDUFA VIII. FDA indicated if the PDUFA payroll target was greater than the actuals, the difference in dollars would be reserved in the operating reserve specifically and exclusively for reviewer staff payroll. This comparison of PDUFA payroll targets against PDUFA payroll actuals would be updated for each subsequent year of PDUFA VIII. FDA acknowledged that while payroll could be dynamic, the payroll target would be consistent, though the target would be subject to inflation to account for the time value of money.

FDA then detailed how it expected PDUFA payroll dollars to shift to the Shared Services organization. FDA had previously explained how the Agency is working to consolidate many non-review functions that previously existed in the Centers. FDA indicated the result will be an increase in Shared Services consumed by PDUFA to replace the non-review services removed from the Centers. FDA indicated that if the Agency did not spend all of the PDUFA funds shifted to Shared Services, the result would be an increase in the operating reserve, all else being equal. The operating reserve increase would likely contribute to a larger downward adjustment when fees are set, assuming the operating reserve cap is exceeded, effectively returning those user fee funds to Industry.

Industry emphasized the need for a tracking mechanism for Shared Services similar to the tracking, reserving, and reporting approach to maintain transparency and accountability on the review staff positions. FDA proposed providing additional detail on the Shared Services obligations and expenditures in the five-year financial plan and suggested the third-party independent study (discussed on January 22nd as part of the Adjustment Discussion topic) could also include administrative areas to evaluate for efficiency gains. Both parties agreed to further consider transparency mechanisms, with plans to continue discussions at the Thursday meeting.

FDA requested feedback on the proposal to limit orphan application fee exceptions and program fee exemptions to only orphan-indicated products, which Industry agreed to provide by Thursday.

Wrap-Up and Next Steps

The goal for the next meeting on February 5th will be to discuss the proposed revenue framework and discuss Industry's perspective on FDA's orphan drug proposal.