Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

February 24, 2026 | 3:30pm–5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To discuss the updated PDUFA VIII financial ledger and to revisit the finance negotiation approach after the previous week's discussion.

PARTICIPANTS

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

MEETING SUMMARY

Industry and FDA reflected on the discussion around the FY 2025 PDUFA Financial Report information provided in the previous week's meetings. Industry advocated for increased transparency and accountability measures to be implemented in the financial framework. The subgroup reviewed the PDUFA VIII financial ledger.

Finance Negotiation Approach

Industry restated its commitment to using PDUFA VIII negotiations to achieve the long-term sustainability of the program, including by mitigating the growth of the user fees and increasing the accountability, transparency, and stability of the program. Industry stated its intention to continue PDUFA VIII negotiations while also seeking additional details from the FDA, through separate channels, on the use of PDUFA VII funds for severance and other related payments, as described by Agency in the February 19, 2026 Finance Subgroup meeting. Industry emphasized that their support of FDA's proposed operating reserve adjustment tracking, reserving, and

reporting (ORA TRR) model was predicated on the assurances that those user fee dollars would be set aside for hiring personnel to restaff the Agency and that unused monies would go back to Industry through an operating reserve adjustment. Industry stated that those assurances were undermined when it learned in the meeting on February 19, 2026 that PDUFA funds have been used to fund a portion of the severance payments made to staff who were subject to the 2025 reduction-in-force (RIF) action. Industry indicated they seek to continue building on the subgroup's progress, but to do so, it would require enhanced measures related to how funds are used and enhanced transparency on PDUFA financials. Industry emphasized the crux of their concern was that controls be in place to ensure funds are used to support human drug review.

FDA explained that the mix of funds used to pay severance is consistent with how payroll was paid out for the employees subject to the RIF. FDA noted that FDA is legally obligated to pay severance to those separated employees that earn it.

FDA further stated that the discussed reduction in the base revenue to reflect administrative efficiencies is only possible because of the RIF, and the severance payments were required as a result of the RIF. As such, FDA asserted that Industry would be realizing a net financial benefit following from the severance payments. Industry noted that it had not asked for these RIFs. Industry noted that PDUFA funds were intended to be used for the human drug review program, and it is Industry's position that severance is not a covered expense under PDUFA. FDA explained that its position is that severance payments are a covered expense under PDUFA.

The subgroup discussed whether additional transparency mechanisms could be implemented. Both FDA and Industry agreed to reflect on the model and the most productive path forward before reconvening to continue negotiations.

PDUFA VIII Ledger

FDA presented the updated financial ledger to track the resource impacts of agreements across subgroups. FDA expanded the level of detail on full-time equivalent (FTE) and direct costs, per previous subgroup conversation, and presented a summary of total changes. The subgroup discussed how negotiated FTEs could be tracked in PDUFA VIII.

Next Steps

The goal for the next meeting is to determine how the potential financial framework package can be further strengthened with transparency and accountability measures.