Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

January 27, 2026 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To review updates to the PDUFA VIII ledger, address Industry questions about FDA's adjustment concept, and determine next steps for resolving outstanding negotiation items.

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		
Stacy Yung	CDER		

MEETING SUMMARY

FDA and Industry reviewed updates to the PDUFA VIII ledger. Industry asked questions about FDA's concept for a potential efficiency adjustment informed by a third-party assessment. FDA shared the outstanding negotiation items to be completed in subsequent meetings. Industry agreed to bring their perspective on where the subgroup has reached alignment in the following meeting.

PDUFA VIII Ledger

FDA provided updates to the PDUFA VIII ledger, reporting that several line items were added. Both parties noted there will likely be further updates pending agreements from other subgroups. Industry asked how the ledger would be incorporated into the financial framework. FDA explained that discontinued activities would be removed from direct costs while new full-time equivalents (FTEs) might be addressed through base or additional dollar amount adjustments.

FDA noted the subgroup will need to discuss the phasing of additional FTEs over PDUFA VIII, as applicable.

Industry Questions on Adjustment Topic

Industry sought further clarity on FDA's concept to assess efficiencies; in particular, Industry sought clarity on baseline establishment, measurement methodologies, and implementation mechanisms. In response to Industry's question about how FDA would set a performance baseline, FDA stated that these questions would be best addressed by an appropriate study design to be developed by a third-party evaluator.

Industry inquired about the timing of the proposed third-party study, to which FDA explained the stated timeline would allow for sufficient data collection to complete a robust assessment. In responding to Industry's question about how FDA would include the adjustment in the financial model, FDA indicated there would need to be language in statute that creates the space for this adjustment, and then additional language in the commitment letter to describe the process for how the study would be conducted.

Industry emphasized their view of efficiency as a continuous improvement journey rather than a one-time event, urging FDA to consider ongoing tracking of efficiencies and potential adjustments. FDA acknowledged this perspective and clarified that the proposal is for a one-time adjustment that may be scheduled over the remainder of PDUFA VIII after the third party study.

Topic Planning and Next Steps

FDA and Industry reviewed a list of outstanding items the financial subgroup will need to complete and discuss means of completing each item.

The goals for the next meeting on January 29th will be to continue discuss Industry's perspective on subgroup alignment and the details of the proposed operating reserve adjustment (ORA) tracking, reserving, and reporting approach.