



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

March 5, 2026 | 1:00pm-3:00pm

FDA White Oak Campus, Silver Spring, MD and Virtual Format (Teams)

MEETING PURPOSE

To review updates to the PDUFA VIII ledger, to summarize finance subgroup discussions to date, and to provide FDA's substantive response to the ideas outlined by Industry.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kate Greenwood	OCC
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CDER
Joshua Kirk	OO/OFBFA
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)
Drew Sansone	BIO (Alkermes)

MEETING SUMMARY

FDA and Industry reviewed updates to the PDUFA VIII ledger. The subgroup assessed a table summarizing the status of finance deliberations to date. FDA offered feedback on the additional ideas presented by Industry in their document, 'Finance Path Forward'. FDA and Industry assessed outstanding items to be completed by the subgroup.

PDUFA VIII Ledger

FDA provided a revised version of the ledger, reflecting recent decisions across subgroups. The parties noted that outstanding finance subgroup discussions may necessitate additional line items in the ledger.

Negotiations to Date

Per Industry request, FDA presented a summary table describing the current state of finance proposals. FDA and Industry conferred to validate their respective understandings of topics and their negotiation status. The parties agreed upon minor changes to ensure the summary was reflective of the latest subgroup developments.

FDA's Response to Industry's 'Finance Path Forward'

FDA acknowledged the hard work that contributed to the 'Finance Path Forward' document and the informative responses offered by Industry in the previous meeting. FDA indicated the Agency could agree to certain Industry proposals. Firstly, FDA could agree to the inflation adjustment being taken after any enterprise performance adjustment (EPA) is implemented. Secondly, FDA is aligned with Industry that the funds set aside in the operating reserve tracking, reserving, and reporting (OR TRR) would be used for the sole purpose of hiring and retaining human drug review staff. Language to this effect would be captured in the PDUFA VIII commitment letter and/or statute, as appropriate. Shared Services would be subject to enhanced transparency in the PDUFA Five-Year Financial Plan. FDA also agreed in concept to enhanced reporting on payroll and other obligations in the annual Finance Report.

To address Industry's proposal regarding technical staff meetings, FDA stated the Agency could agree to offering one technical staff meeting to occur after the fee-setting Federal Register Notice each year, to occur in the August to September timeframe. Topics for this meeting can include anything in the fee-setting or financial realm for PDUFA. This meeting would be expected to include Industry and have published meeting minutes for transparency.

FDA stated it is unable to agree to Industry's proposal to decrease the operating reserve bounds to 9 - 11 weeks. FDA had previously suggested a decreased 10 - 12-week range in support of standardization goals across user fee programs and could not deviate from this. FDA noted any further decrease in the operating reserve cap could heighten the risk for both Agency and Industry if, for example, a perfect storm of under-collections and a government shutdown were to occur.

FDA asserted it is unable to agree to Industry's proposal to make the capacity planning adjustment (CPA) a zero value for one year if the EPA study recommends an adjustment and such adjustment is not taken. FDA expressed hesitancy to implement constraints on the financial framework that are dependent on such a novel, unprecedented concept as the EPA. The subgroup considered hypothetical outcomes of the EPA and the resulting impact on the CPA and FDA workforce. FDA provided a counterproposal to increase the OR TRR baseline to the FY 2025 payroll instead of FY 2024, which would result in an increase in the OR TRR payroll target. The Agency reasoned this higher baseline would better meet the goal of Industry's CPA/EPA proposal while also keeping the framework mechanisms simpler and avoiding unforeseen risks. Industry said they would consider FDA's counterproposal.

To Do List and Next Steps

FDA and Industry discussed how finance subgroup agreements could be reflected in statute and the commitment letter. The subgroup reviewed pending action items, such as the drafting of the justifications document. Industry expressed they would reflect upon the financial framework material covered in the meeting and provide a response as soon as is feasible.