



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

December 4, 2025 | 1:00pm-3:00pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To continue discussion from last meeting and to circle back on FDA's operating reserve adjustment and trigger proposals.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kate Greenwood	OCC
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)

MEETING SUMMARY

The subgroup discussed shared FDA-Industry financial goals and continued the discussion on Industry's thinking regarding a funding model, as well as FDA's operating reserve adjustment and triggers proposals.

Follow-up Discussion from Last Meeting

FDA presented a draft goal statement to facilitate FDA and Industry conversation on the goals and approach to funding the program in PDUFA VIII. The subgroup discussed.

FDA presented their understanding of the funding model proposed by Industry at the last meeting and asked for Industry to clarify whether FDA's understanding was accurate.

After a brief caucus, Industry agreed to provide an illustrative example to demonstrate its thinking at the next meeting.

Operating Reserve Adjustment

FDA explained that its proposal to make the operating reserve floor discretionary was intended to address perceived concerns from Industry by avoiding small upward adjustments. Industry reiterated they had no concerns with small upward adjustments.

The group discussed Industry's proposal on the operating reserve adjustment. FDA indicated it would like to consider this proposal further within the context of a broader framework for an agreement at the subgroup level.

FDA noted that there may be an approach to addressing the remaining issues related to the overall funding model as a package. FDA agreed to share a written version of this potential framework with Industry before the next meeting.

Triggers

Industry shared that it viewed the triggers as an important mechanism to protect the PDUFA program by ensuring that an appropriate amount of non-user fee funding is provided to the program. It noted that increasing the compliance threshold on the trigger could result in Industry funding an even greater share of the PDUFA program. As such, Industry stated that it does not support adjusting the compliance threshold on the trigger. FDA noted that it would revisit this topic after consulting internally.

FDA asked about Industry's view regarding the technical change to update the statutory language to reflect the 2025 trigger amounts without changing the value of these numbers. Industry said it would like to discuss this at a subsequent meeting.

Wrap-Up and Next Steps

The goals for the next meeting on December 9th will be to discuss the model that Industry is considering as well as the framework that FDA is envisioning.