



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

December 9, 2025 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To continue discussion from the previous meeting, and for FDA to present their proposed framework for agreement.

PARTICIPANTS

FDA

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

Industry

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

MEETING SUMMARY

FDA presented their proposed financial framework and discussed the framework with Industry.

FDA Framework

FDA presented a potential framework to address the overall funding model at the subgroup level. This framework included savings reflecting expected administrative efficiencies, discontinuation of some direct costs, updates to the framework for the operating reserve adjustment, recognizing that the capacity planning adjustment will not add additional positions until review staff have been backfilled, and discontinuing the strategic hiring and retention adjustment.

Industry indicated that they saw issues with the model, as they believe the model was likely to result in FDA collecting more than is needed and then offsetting the fee amounts with the operating reserve adjustment. Industry indicated it would prefer a different model and noted that it is working to develop its counterproposal.

Industry indicated that the direct costs in PDUFA VII were not intended to continue in PDUFA VIII and that these amounts are subject to renegotiation in any subsequent reauthorization of PDUFA. FDA stated that this was not consistent with its view of the PDUFA VII agreement, as some of the direct costs, like those for Sentinel for example, were indicated as recurring costs.

FDA addressed Industry's clarifying questions on other elements of this framework.

Industry noted they plan to share their model in a subsequent meeting.

Wrap-Up and Next Steps

The group then discussed the remaining meeting schedule for December.

The goals for the next meeting on December 11th will be to discuss the FDA's proposed technical change to trigger statutory language and to revisit the FDA's fixing fee loopholes proposal.