



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

December 02, 2025 | 3:30pm-5:00pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To review the data prepared by FDA and to discuss potential changes to the financial structure to reflect administrative efficiencies.

PARTICIPANTS

FDA

Joshua Barton	CDER
Angela Granum	CDER
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CDER
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)
Drew Sansone	BIO (Alkermes)

MEETING SUMMARY

The subgroup discussed potential administrative efficiencies, including a discussion of shared services consolidation efforts. FDA addressed Industry's clarifying questions.

FDA and Industry reached an agreement at the subgroup level on the patch test exemption proposal.

Administrative Efficiencies

FDA presented data describing non-review staffing levels expected to result from its shared services consolidation efforts. FDA addressed Industry's clarifying questions regarding these data.

FDA and Industry explored potential options to ensure that PDUFA funding is available when needed to support the appropriate staffing levels.

The discussion concluded with the subgroup agreeing to further explore potential paths forward in subsequent meetings.

Wrap-Up and Next Steps

FDA and Industry reviewed the agenda for the next meeting and briefly discussed the planned topics with the time remaining in this meeting.

Industry indicated that they would be able to agree at the subgroup level to the proposal to exempt patch tests for the diagnosis of allergenic contact dermatitis from paying PDUFA fees.

FDA noted that implementing the discretionary floor for the operating reserve adjustment was intended to benefit Industry by avoiding small upward adjustments. Industry indicated that incremental adjustments to the operating reserve are not an issue from its perspective. The subgroup will further discuss the operating reserve proposal at the next meeting.

The goals for the next meeting on December 4th will be to continue the discussion from this meeting, and to revisit the operating reserve adjustment and trigger proposals.