Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

November 6, 2025 | 1:00pm-3:00pm

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

MEETING PURPOSE

To discuss schedule for in-depth finance proposal review, address clarifying questions on proposals, and provide an overview of the components of PDUFA fee setting.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Steve Berman	BIO
Angela Granum	CDER	Carl Garner	PhRMA (Eli Lilly)
Christine Hunt	OCC	Kelly Goldberg	PhRMA
Kate Greenwood	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

The group discussed and aligned on a proposed schedule to discuss each proposal over the next few weeks. FDA addressed follow-up clarifying questions regarding the following proposals: fixing fee loopholes, harmonizing triggers for efficiency and resilience, enhancing operating reserve adjustment flexibility, patch test exemption, and technical changes to fee administration.

Industry then addressed a clarifying question regarding its proposal to discontinue funding of PDUFA VII additional direct costs.

FDA provided an overview of the fee-setting process and the base revenue.

Fixing Fee Loopholes (FDA Proposal)

FDA clarified that its proposal would not impact any products that only have orphan-designated indications.

Harmonizing Triggers for Efficiency and Resilience (FDA Proposal)

FDA clarified that it is proposing to align the spending trigger compliance threshold to match the Biosimilar User Fee Act (BsUFA) program's 15% compliance threshold and to provide FDA with additional flexibility.

Enhancing Operating Reserve Adjustment Flexibility (FDA Proposal)

FDA answered clarifying questions regarding how the operating reserve adjustment works and how FDA manages the PDUFA carryover balance.

Patch Test Exemption (FDA Proposal)

FDA clarified that there have been no fees collected from patch test products and thus there would be no impact on the finances of the PDUFA program from this proposal.

Technical Changes to Fee Administration in Statute (FDA Proposal)

FDA indicated it would be able to share its proposed statutory language for the technical changes soon.

Allowing PDUFA VII Provisions to Sunset at their Negotiated Expiration (Industry Proposal)

Industry clarified that its proposal is to allow some provisions in PDUFA VII to sunset at their negotiated expiration at the end of PDUFA VII, including the funds related to Sentinel. Industry indicated it would confirm its intention regarding the additional direct costs for cell and gene therapy. FDA indicated that a small amount of the direct costs for resource capacity planning include time reporting license costs, which would be important to maintain. FDA and Industry agreed to refer further discussion of the impact of these proposed funding cuts to the relevant subgroups.

Fee and Revenue Primer

FDA provided an overview of the PDUFA fee and revenue setting process and explained each component contributing to program and application fee calculations.[1]

FDA clarified that the managerial adjustment component of the Capacity Planning Adjustment has only resulted in a reduction of the adjustment and that the managerial adjustment has

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[1] *The materials used for this discussion were based on the materials from the FY2024 Financial Transparency and Efficiency public meeting. See slides 8 – 26: https://www.fda.gov/media/179317/download?attachment*

historically been decided by the Center Directors in the Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

FDA clarified that any Operating Reserve Adjustment only impacts the revenue amount for the current year and does not impact the base revenue for subsequent years.

FDA showed data highlighting that the majority of the application fee increase in fiscal year 2024 was driven by variability in the number of fee-paying applications in prior years. The subgroup discussed how FDA estimates the number of fee-paying applications for fee-setting purposes, including its traditional use of three-year averages. FDA noted it had used 10-year averages recently to reflect longer-term numbers and to help to mitigate application fee increases.

After talking through the fee-setting process, FDA discussed the current financial state of the PDUFA program. FDA indicated the current financial structures are in place to manage the revenue amounts. FDA explained that it is planning to rebuild review and support functions and acknowledged that this rebuilding will take time. FDA referenced the ongoing efforts to consolidate support functions and stated that FDA expects streamlining and efficiencies to result from this consolidation. FDA noted that the operating reserve adjustment would be used, if needed, to adjust the annual revenue amounts down, should the operating reserve balances exceed the 14-week statutory limit in PDUFA VII. FDA noted that, given the current review staff vacancies and assuming all else equal, the Capacity Planning Adjustment, as designed, would be expected to result in no additional positions until the review functions are re-staffed.

FDA shared data on the impact of the Capacity Planning Adjustment, detailing a long-term downward trend in resources allocated through the CPA and that no positions were added in fiscal year 2026 as a result of the managerial adjustment.

Industry clarified that their proposal aims to curb the growth of the program and ensure its long-term sustainability. FDA and Industry discussed potential alternatives to this proposal.

FDA addressed Industry's clarifying questions regarding the state of the PDUFA program finances and the fee-setting process.

Next Steps

The goals for the next meeting on November 13th will be to discuss the operating reserve adjustment, trigger flexibility, and patch test exemption proposals in detail.