Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

November 4, 2025 | 3:30pm–5:00pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To establish a process, share proposals, and align on schedule for in-depth discussions regarding the PDUFA program finances.

PARTICIPANTS

FDA		Industry	
Joshua Barton	CDER	Rob Berlin	BIO (Vertex)
Yanming Chae	CBER	Steve Berman	BIO
Emily Ewing	CDER	Carl Garner	PhRMA (Eli Lilly)
Angela Granum	CDER	Kelly Goldberg	PhRMA
Christine Hunt	OCC	Kristy Lupejkis	PhRMA
Kristopher Hoover	CDER	Alison Maloney	PhRMA (Bayer)
Rebecca Kemp	CBER	Drew Sansone	BIO (Alkermes)
Joshua Kirk	OO/OFBA		
Andrew Kish	CDER		
Stacy Yung	CDER		

MEETING SUMMARY

After introductions, the following topics were addressed:

PDUFA Finance Group Role and Process Discussion

FDA highlighted the expected role of the Finance subgroup, which is to contribute to any finance-relevant Commitment Letter language, to lead discussion of any proposed statutory changes, which would be limited to the fee and financial sections of the PDUFA statutory language (sections 735 & 736 of the Federal Food, Drug, and Cosmetic Act), and to lead development of the Justifications Document, which explains any statutory changes.

Industry agreed with FDA's proposed role and process for the Finance subgroup.

FDA Financial Perspective

FDA provided a brief overview of the Agency's general perspective of the state of the PDUFA financial mechanisms. FDA asserted the financial structure has largely worked as intended and believes the core financial components must be maintained to ensure consistency. FDA emphasized that stable PDUFA finances are critical to the long-term sustainability of the program and noted that PDUFA VIII will not be implemented until fiscal year 2028.

FDA noted many measures of workload have outpaced staffing levels going back across the last three PDUFA authorizations.

FDA recognized concerns raised about the application fee amounts. FDA added that the most significant variable leading to the application fee increasing has been the variability in the number of fee-paying applications since about 2020. FDA observed that the variability in fee-paying applications has also created significant user fee collections uncertainty.

Fixing Fee Loopholes

FDA introduced a proposal intended to prevent a product seeking one or more non-orphan indications to benefit from the orphan application exception and the orphan program fee exemption. FDA proposed that if an application receives the orphan application exception, the application is approved, and the sponsor later submits a supplement seeking to expand its indications to a non-orphan indication, the sponsor should at that time pay the application fee. FDA noted that since 2018 it is aware of a few instances of drugs that were approved for orphan indications subsequently being approved for non-orphan indications.

Additionally, under this proposal, any approved products that have non-orphan indications would not be eligible for the program fee exemption. FDA observed that the number of approved products that currently benefit from the orphan program fee exemption is small.

FDA stated that under the proposal, there would be no change in fee exceptions or exemptions for products that only have orphan-designated indications.

FDA answered Industry's clarifying questions.

Harmonizing Triggers for Efficiency and Resilience

FDA introduced a proposal to update aspects of the PDUFA appropriations and spending triggers. FDA explained that harmonizing aspects of the triggers across different user fee programs would help to realize administrative efficiencies. In addition, FDA mentioned that additional flexibilities around the triggers may be helpful in an uncertain budgetary environment. The proposed changes include technical updates to the statutory language as well as harmonization of the spending trigger compliance threshold with other programs.

FDA answered Industry's clarifying questions.

Enhancing Operating Reserve Adjustment Flexibility

FDA introduced a proposal to change the statutory floor of 10 weeks of operating reserves to a discretionary floor of 10 weeks, consistent with the Generic Drug User Fee Amendments (GDUFA). FDA noted that this discretion would mitigate the need for minor adjustments should the operating reserves be just below the 10-week amount.

FDA answered Industry's clarifying questions.

Patch Test Exemption

FDA introduced a proposal to exempt patch tests for the diagnosis of allergenic contact dermatitis from paying PDUFA fees. These products became fee-liable when allergenic products were added to the scope of PDUFA under PDUFA VII. These patch test products are low revenue products and unlikely to submit applications for additional allergens given the fee requirements. This proposal would be similar to the exception added for skin-test diagnostic products in PDUFA VII.

Technical Changes to Statute

FDA noted the Agency had four other proposals to update other aspects of the PDUFA fee statutory sections for efficiency and clarity purposes.

Industry Proposals

Industry expressed support for the PDUFA program overall, voiced concerns with the growth of the program, and emphasized its interest in PDUFA realizing efficiencies. Industry affirmed its commitment to supporting FDA.

Industry noted significant user fee resources provided over the last three PDUFA cycles and annual adjustments for workload taken by FDA through the capacity planning adjustment over the same time period and introduced a set of proposals to ensure the efficiency, accountability, transparency, and stability of the program. Specifically, by limiting additional full-time equivalents (FTEs) to mitigate the growth of the program, capping the inflation adjustment, removing the capacity planning adjustment from the annual PDUFA user fee setting process, reducing the carryover balance cap, and allowing some provisions from PDUFA VII to sunset at their negotiated expiration at the end of PDUFA VII, i.e., the strategic hiring and retention adjustment and additional direct costs.

Industry addressed FDA's clarifying questions.

Next Steps

The goals for the next meeting are to align on a schedule for discussing FDA and Industry proposals in detail, to provide time for additional clarifying questions, and for FDA to present an overview of the fee-setting process and the base revenue.