Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

December 11, 2025 | 1:00pm–3:00pm

Virtual Format (Teams)

MEETING PURPOSE

To continue discussion on the technical change to trigger statutory language and the fixing fee loopholes proposal.

PARTICIPANTS

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

MEETING SUMMARY

FDA and Industry discussed technical changes to the statutory language for triggers and the fixing fee loopholes proposal. Industry expressed conceptual agreement with the technical trigger changes but requested review of statutory language before final approval. Industry did not support the fee loopholes proposal because they are concerned it could have negative impacts on rare disease drug development. Industry also reiterated its disagreement with the FDA's characterization of the existing fee exemptions for orphan products as loopholes.

Trigger – Technical Change to Statutory Language

FDA's proposal for technical change to the trigger statutory language aims to simplify spending trigger calculations by writing the 2025 trigger amounts into statute while concurrently updating the adjustment factor. FDA noted this proposal reflects an interest in establishing more

consistency in the common mechanisms across the user fee programs. FDA clarified that this technical change would not change the actual effective values but would update the starting point for the trigger calculations by converting the 1997 numbers to their 2025 equivalents.

Industry indicated it may be open to this proposal but that it would need to be considered as a part of a broader package agreement. FDA committed to sharing draft statutory language to demonstrate its intention with this proposed technical change.

Fixing Fee Loopholes Proposal

(See Finance Subgroup meeting minutes from 11/4/25, 11/6/25, and 11/18/25 for background on this proposal.)

Industry stated that it does not agree with characterizing this issue as a loophole. Industry expressed its view that this is how the statute is designed and intended to operate to incentivize the development of orphan drug products for rare diseases. Industry stated its view that this situation was a foreseeable outcome and had been previously acceptable to all stakeholders.

Industry also expressed concerns about the proposal's potential impact on rare disease drug development, particularly for small and mid-sized companies. They explained that imposing fees could disincentivize companies from pursuing rare disease drug development in favor of larger market opportunities, ultimately disadvantaging the rare disease community that relies heavily on smaller companies for innovation.

FDA noted its expectation that application fees were unlikely to disincentivize development of what are significantly grossing products based on sales data. FDA noted that under the current fee structure, the sponsors that are paying fees will be paying higher fees to account for the fact that sponsors of the drugs at issue do not pay fees. Industry stated that FDA's proposal would be seen as a disincentive to rare disease drug development, particularly by smaller companies, and this may impact their business decisions and risk taking. Industry noted that the current fee structure was designed with the understanding that fee-paying companies would bear larger fees to support development in neglected disease areas, and that this arrangement reflects a deliberate decision to encourage rare disease research.

The group noted that it would need to follow up on this proposal in a subsequent meeting.

Wrap-Up and Next Steps

The goal for the next meeting on December 16th will be for Industry to present their proposed funding framework.