



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Finance Subgroup

December 16, 2025 | 3:30pm-5:00pm

Virtual Format (Teams)

MEETING PURPOSE

To understand Industry's proposed funding framework.

PARTICIPANTS

FDA

Joshua Barton	CDER
Emily Ewing	CDER
Angela Granum	CDER
Kristopher Hoover	CDER
Christine Hunt	OCC
Rebecca Kemp	CBER
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

Industry presented their proposed funding framework. The subgroup discussed. Industry agreed to develop illustrative examples to clarify its proposed approach.

Industry Proposed Model/Concept

Industry began by presenting modifications to FDA's drafted goal statement. Industry emphasized they want to ensure that PDUFA funding is available when needed to support the appropriate staffing levels at the Agency, aligned with PDUFA goals and priorities.

Industry proceeded to describe their proposed funding framework. Their framework included base funding modified each year to align with the full-time equivalent (FTE) level in the program at the beginning of the previous year, a reduction representing administrative efficiencies, a capped inflation adjustment, a strategic restaffing adjustment that provides funding for restaffing of FTEs, changes to the capacity planning adjustment, and a reduction to the cap on the operating reserve adjustment to 12 weeks. The total revenue for the Fiscal Year would be the

summation of the dynamic base and the adjustments. Industry stated that it believes that such a model would allow FDA the financial flexibility to restaff as quickly as possible, while sizing the PDUFA VIII annual funding for staffing to the realistic ability to hire staff, based on FDA hiring process considerations.

FDA expressed concerns about the implication of the lack of financial predictability of the proposed model. FDA emphasized that predictability of funding levels has been a fundamental element of the program since its inception in 1993, noting that the fee structure was designed from the beginning to ensure the stable, predictable funding that is necessary to effectively manage operations. FDA maintained that the current process has been carefully designed and negotiated with Industry over multiple cycles to provide program and financial stability. FDA asserted that a complex funding framework with many variables creating uncertain funding levels from year-to-year would undermine FDA's ability to efficiently and effectively manage the financial resources of the PDUFA program. Industry replied that it believes that the proposed model supports a stable and sustainable program, with appropriate and adequate certainty around funding, while adapting to the modern environment not envisioned over previous cycles.

Industry acknowledged that the implementation mechanics of their model need to be further detailed. FDA requested illustrative examples to better understand how the model would function across multiple years. Industry committed to providing illustrative examples as soon as feasible.

Wrap-Up and Next Steps

The goals for the next meetings will be to continue discussion of Industry's proposed framework with illustrative examples.