Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

November 6, 2025 | 3:30pm – 5:00pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To introduce FDA's proposal to create fee incentives for domestic drug development and to share updates from the subgroups.

PARTICIPANTS

FDA	
Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai	CDER
Amy Ramanadham	CDER
Larry Lee	CDER
Josh Barton	CDER
Sonday Kelly	CBER
Katie Rivers	CBER
Christine Hunt	OCC
Kate Greenwood	OCC
Karim Mikhail*	OC

**These attendees departed before subgroup progress updates.*

INDUSTRY	
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Adora Ndu	BIO (Bridge Bio)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Lucy Vereshchagina	PhRMA
Glen Murphy*	CHPA (Kenvue)
Marcia Howard*	CHPA
David Spangler*	CHPA

MEETING SUMMARY

FDA presented goals for the proposal to create fee incentives for domestic drug development and responded to clarifying questions from Industry. Following a break, the FDA and Industry subgroup leads provided a summary of their subgroup's accomplishments from this week and their plans for upcoming weeks.

Fee Incentives for Domestic Drug Development

FDA presented a proposal to create fee incentives for domestic drug development. FDA shared its goal is to anchor clinical development in the United States (U.S.) by reducing the application fee for programs that conduct Phase 1 clinical trials in the U.S. Under this proposal, development programs that do not conduct Phase 1 clinical trials in the U.S. would experience higher fees, and they would begin paying fees annually after submitting an Investigational New Drug (IND) application to FDA.

Industry inquired about why the proposal leverages user fees to incentivize domestic drug development, as opposed to leveraging efficiencies that could accelerate the time required for drug development and review. FDA clarified that process efficiencies intended to accelerate clinical development are also of interest to the Agency, but outside of scope of the PDUFA negotiations. Industry also asked clarifying questions about how FDA would operationalize the fee incentives, and FDA agreed that operational details of the proposal (e.g., criteria for reduced application fees, timing of fee payments, impacts on small and midsize companies) will be discussed in more detail at future negotiations meetings.

Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Post-Market Safety; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups summarized their accomplishments and plans for next steps. All subgroups achieved the objectives for the first week, which were to review FDA and Industry proposals, at a high level, and create a tentative schedule for discussing the proposals in more detail. The subgroup leads from Pre-Market, Post-Market Safety, and CMC agreed to coordinate with the subgroup leads from Finance to facilitate conversations that involve resources. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

FDA and Industry agreed that the first week of negotiations meetings was productive. FDA agreed to propose a plan for future discussions about the fee incentives proposal. FDA and Industry agreed that, in addition to progress updates from the subgroups, future meetings in November and December will include (1) readouts from the Stakeholder Consultation Meetings, (2) discussion of FDA's proposal to limit the small business waiver to sponsors based in the U.S., and (3) proposed edits to the Information Technology and Cell and Gene Therapy sections of the commitment letter. FDA agreed to document a schedule with proposed dates for each discussion and share it with Industry.