Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

November 13, 2025 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

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

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Annetta Beauregard	BIO
Emily Ewing	CDER	Rob Berlin	BIO (Vertex)
Mary Thanh Hai	CDER	Steve Berman	BIO
Larry Lee	CDER	Adora Ndu	BIO (Bridge Bio)
Josh Barton	CDER	Drew Sansone	BIO (Alkermes)
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Donna Boyce	PhRMA (Pfizer)
Christine Hunt	OCC	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis	PhRMA
		Alison Maloney	PhRMA (Bayer)
		Katrin Rupalla	PhRMA (J&J)
		Lucy Vereshchagina	PhRMA
		Glen Murphy*	CHPA (Kenvue)
**These attendees departed before subgroup progress updates.*		Marcia Howard*	CHPA
		David Spangler*	CHPA
		Carolyn Hermann*	CHPA
		Erin Oliver*	CHPA (Haleon)

MEETING SUMMARY

FDA collected perspectives from Industry on FDA's America First proposal to create fee incentives for domestic drug development. FDA also clarified timelines for reviewing meeting minutes and the schedule for upcoming Steering Committee meetings. 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.

Feedback on FDA's America First Fee Incentives for Drug Development Proposal

Industry provided their perspectives on the America First fee incentives proposal introduced by FDA at the November 6th Steering Committee meeting. Industry explained that they share the goal of enhancing U.S. competitiveness and incentivizing early drug development in the United States and acknowledged a trend in drug development programs initiating outside the United States (U.S.) due to time, cost, and complexity. Industry emphasized the importance of a predictable and stable PDUFA for innovation. Industry expressed concerns that PDUFA may not be the best vehicle for the desired outcome, given 90% of drugs fail before reaching the marketing application and related PDUFA fee stage. Industry noted that the fee incentives proposal could create unintended consequences that may increase the burden of domestic drug development and drug development generally, in particular for small and emerging biotechnology companies. Industry also expressed concerns that the proposed fee structure would be difficult to administer. They suggested that a proposal to address the challenges with domestic drug development should address the root causes – namely, time, cost, and complexity - that drive companies to initiate drug development outside the United States, and they noted that some root causes are outside of the scope of the PDUFA program. Finally, Industry emphasized incentives such as shortening phase 1 review times, reducing clinical trial administrative burdens such as by standardizing documents and processes, leveraging technologies, expanding the use of Single Institutional Review Board (IRBs), further clarifying toxicology and new approach method data requirements and further supporting the application of quality risk management to chemistry, manufacturing, and controls (CMC) are more effective than penalties. FDA agreed to revisit the fee incentives proposal at a later meeting.

Update on Logistics

FDA and Industry discussed and agreed on the timeline for drafting and review of meeting minutes. FDA proposed a schedule for the topics to be covered at Steering Committee meetings for the remainder of the calendar year. FDA's proposed schedule included monthly reports on the perspectives shared by patient and consumer groups at the Stakeholder Consultation Meetings that occur in parallel with FDA-Industry negotiations, as well as discussion of FDA's proposals to limit the small business waiver to U.S.-based companies and to revise the Information Technology and Cell and Gene Therapy sections of the PDUFA commitment letter. FDA also proposed to revisit the fee incentives proposal. Industry agreed to provide any feedback on the schedule following the meeting.

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 transitioned to detailed discussions of proposals this

week, and the leads expressed that their subgroups plan to continue detailed discussions in accordance with the schedules established last week. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

The goals for the next meeting on November 18th will be to review FDA's proposed goals for each subgroup to accomplish by the end of the calendar year and to review FDA's America First proposal to limit the small business waiver to U.S.-based companies.