Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

November 4, 2025 | 9:30am–10:30am

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To establish expectations for reauthorization meetings and agree on reauthorization ground rules, provide background and context about the PDUFA program, and agree on a schedule for upcoming meetings.

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Annetta Beauregard	BIO
Emily Ewing	CDER	Rob Berlin	BIO (Vertex)
Mary Thanh Hai	CDER	Steve Berman	BIO
Amy Ramanadham	CDER	Adora Ndu	BIO (Bridge Bio)
Larry Lee	CDER	Drew Sansone	BIO (Alkermes)
Josh Barton	CDER	Derek Scholes	BIO
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Donna Boyce	PhRMA (Pfizer)
Katie Rivers	CBER	Carl Garner	PhRMA (Eli Lilly)
Christine Hunt	OCC	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis	PhRMA
		Alison Maloney	PhRMA (Bayer)
		Lucy Vereshchagina	PhRMA
		Glen Murphy	CHPA (Kenvue)
		Marcia Howard	CHPA
		David Spangler	CHPA

MEETING SUMMARY

The meeting was focused on establishing shared expectations for the negotiations process and a shared understanding of the PDUFA program.

Expectations and Ground Rules

FDA shared best practices for efficient and effective negotiations and reviewed the ground rules governing PDUFA VIII negotiations. FDA and Industry agreed to ratify the ground rules with no additional edits. FDA also presented the operating processes and rules for conducting negotiations in a hybrid environment. Industry acknowledged the new statutory requirements around posting of meeting minutes but expressed concerns with the proposed short turnaround times for the trade associations to coordinate review of draft meeting minutes and requested additional time to review the drafted meeting minutes. FDA agreed to propose a new timeline.

PDUFA Program Background and Context

FDA discussed trends in PDUFA workload in terms of submission volume and review performance against the PDUFA VII goals. FDA highlighted that although submissions for New Drug Applications (NDAs) and Biologic Licensing Applications (BLAs) increased during PDUFA VI (2018-2022), submission volume has been variable over the last four years. FDA also shared that supplement submissions, active commercial Investigational New Drug (IND) applications, and meeting requests have increased steadily since PDUFA V (2013-2017). FDA generally meets review performance goals; however, the timelines for scheduling meetings are a challenge for the Agency.

FDA also shared trends in the percentage of original NDA and BLA submissions reviewed by the Center for Drug Evaluation and Research (CDER) that received a complete response. The percentage of NDA and BLA filings receiving a complete response has varied since PDUFA IV (2008-2012) and in FDA's view doesn't appear to indicate sustained trends. FDA noted that complete responses tend to be associated with certain application attributes, such as non-new molecular entities (NMEs), BLAs, sponsors that are small businesses, and standard applications (as opposed to priority).

FDA reviewed net hiring data for CDER and the Center for Biologics Evaluation and Research (CBER). Industry inquired about challenges with hiring, including the time required to hire and train staff. Industry also inquired about functions affected by the 2025 Reduction in Force.

Schedule and Logistics

FDA and Industry agreed that the Steering Committee will meet twice per week; although, meetings may be cancelled if additional preparation time is needed or there are no topics to discuss. Meetings for the Steering Committee will be held at FDA's White Oak campus in Silver Spring, Maryland, twice per month. Other meetings will be held virtually.

FDA and Industry agreed that, in addition to reviewing the progress of the subgroups, the Steering Committee will discuss proposals from FDA related to establishing fee incentives for domestic drug development and limiting the small business waiver to sponsors based in the United States of America. The Steering Committee will also discuss modifications to the

Information Technology and Cell and Gene Therapy sections of the commitment letter. FDA and Industry established a schedule for discussing these topics in November and December.

Next Steps

The goals for the next meeting on November 6th will be to review FDA's proposal to create fee incentives for domestic drug development and to share updates from the subgroups.