Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

November 13, 2025 | 10:30 am–12:30 pm

Virtual Format

MEETING PURPOSE

To discuss FDA and Industry's detailed proposals and confirm the schedule for negotiation of proposals.

PARTICIPANTS

FDA		INDUSTRY	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Donna Boyce	PhRMA (Pfizer)
Marie Bradley	CDER	Annetta Beauregard	BIO
Meghana Chalasani	CDER	Rob Berlin	BIO (Vertex)
Irene Chan	CDER	Steve Berman	BIO
Kathleen Davies	CDER	Carl Garner	PhRMA (Eli Lilly)
Emily Ewing	CDER	Kelly Goldberg	PhRMA
Sonday Kelly	CBER	Kristy Lupejkis	PhRMA
Andrew Kish	CDER	Alison Maloney	PhRMA (Bayer)
Phillip Kurs	CBER	Adora Ndu	BIO (Bridge Bio)
Mark Levenson	CDER	Katrin Rupalla	PhRMA (J&J)
Janet Maynard	CDER	Drew Sansone	BIO (Alkermes)
Jennifer Mercier	CDER	Lucy Vereshchagina	PhRMA
Paul Phillips	CDER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA presented their detailed proposals on Advancing Real World Evidence, Complex Innovative Designs (CID), Model-Informed Drug Development (MIDD), Streamlining Review of Certain Efficacy Supplements, Meetings Management, and Rare Disease. Industry asked questions about the proposals FDA presented and agreed to continue sharing their questions at the next meeting. FDA presented their initial perspectives on Industry's Facilitating First Cycle Review proposal.

FDA and Industry concluded with agreeing to discuss the Facilitating First Cycle Review proposal in detail at the next meeting.

FDA Detailed Pre-Market Proposal Presentation

FDA presented the details of their proposal topics, with the goal of enhancing and streamlining the review and meetings management processes for PDUFA VIII. The Agency's proposal topics are[1]: (1) Advancing Real-World Evidence (RWE) Program; (2) Complex Innovative Designs (CID); (3) Model-Informed Drug Development (MIDD); (4) Streamlining Review of Certain Efficacy Supplements; (5) Meetings Management; and (6) Rare Disease.

During the Advancing RWE Program proposal presentation, FDA proposed that the program continue with minor modifications to the eligibility criteria to potentially increase the number of submissions accepted. Additionally, FDA presented a rationale for continuing the program, noting the opportunity for focused RWE discussions, continued cross-Center collaboration, and using RWE in regulatory decisions as it continues to evolve.

The CID proposal presentation focused on how the program provides sponsors with a forum to discuss using novel approaches to drug development design. FDA proposed simplifying the current CID meeting process to a regular formal meeting, allowing for more use of the program while ensuring that the appropriate subject matter experts (SMEs) and leadership are present to provide consistent feedback.

In the MIDD proposal, FDA provided an overview of the outputs of the program since its inception, noting increased sponsor demand for the program and FDA's capacity to address growing innovation in drug development. FDA proposed simplifying the current meeting process to a regular formal meeting to shorten the Agency's response times to sponsor meeting requests.

FDA then proposed a Streamlining Review of Certain Efficacy Supplements Pilot to streamline Agency review of certain efficacy supplements that have well-established endpoints, a well-characterized safety profile, and strong evidence of effectiveness. The goal of the pilot is to support earlier decision making, provide sponsors with greater transparency and predictability, and increase efficiency in the review process.

FDA presented on the factors, such as the increase in meeting volume, reviewer workload, and the fixed numbers of FDA signatories defined under the Congressionally approved organizational structure, that affect the Agency's current challenges with achieving meeting scheduling performance goals. To address these challenges, FDA proposed simplifying meeting categories,

[1] FDA proposed to phase out the Split Real-Time Application Review (STAR) Pilot Program during the November 4th meeting. In turn, FDA did not present a detailed proposal for the program during this meeting. Please see the November 4th meeting summary for details.

meeting package timelines, and updating scheduling goals to account for FDA reviewer workload and FDA signatory capacity.

Lastly, FDA proposed to modify PDUFA VII rare disease commitments by incorporating the Rare Disease Innovation Hub (the Hub) to serve as a point of collaboration between CBER, CDER, and external stakeholders. The Hub would use science-focused workshops and feedback meetings to incorporate external feedback and suggestions into FDA rare disease programming. Additionally, FDA proposed to continue the Rare Disease Endpoint Advancement (RDEA) program, which provides a mechanism for sponsors to collaborate with FDA throughout the efficacy endpoint development process.

Industry Questions on FDA Proposals

Industry expressed that they had learned from the Advancing RWE pilot and want to disseminate learnings from it within CDER. Industry noted that they supported multiple RWE-related commitments resourced through industry user fees in the PDUFA VI and PDUFA VII Commitment Letters. Industry also asked questions about the progress made under the RWE program, reasons why companies that were and were not accepted into the RWE Pilot, the process for how companies are accepted, resources used to maintain RWE, and next steps for the pilot.

Industry asked about the CID and MIDD program proposals, focusing on the intent for proposing to change the programs to a formal PDUFA meeting, how learnings from the programs would be applied for regulatory decision-making across the FDA, and resources needed for the proposed commitments.

Industry then asked questions about the Streamlining Review of Certain Efficacy Supplements proposal. Their questions centered on the benefits of the proposal and clarification about the proposed eligibility criteria.

Lastly, in response to the Meetings Management proposal, Industry asked for clarification on the challenges with achieving meeting scheduling and performance goals as well as the process for making the proposed changes. Industry then asked how FDA would ensure meeting scheduling was not further delayed due to the proposed changes. Industry agreed to complete their questions on the Meetings Management and Rare Disease proposals at the next meeting.

Confirming Schedule of Proposal Topic Discussions

FDA and Industry confirmed that they would negotiate Industry's Facilitate First Cycle Review proposal during the next meeting.

Next Steps

The goals for the next meeting on November 18th will be to finish discussing Industry's questions about FDA's detailed proposals and discuss Industry's Facilitate First Cycle Review proposal.