Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 29, 2026 | 10:30 am–12:30 pm

Virtual Format

MEETING PURPOSE

To discuss progress on proposal negotiations along with the draft commitment letter language for Model-Informed Drug Development (MIDD) and Advancing Real-World Evidence (RWE). To discuss the Facilitate First Cycle Reviews proposal.

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
Emily Ewing	CDER	Carl Garner	PhRMA (Eli Lilly)
Sonday Kelly	CDER	Kelly Goldberg	PhRMA
Andrew Kish	CDER	Kristy Lupejkis	PhRMA
Mark Levenson	CDER	Adora Ndu	BIO (Bridge Bio)
Rajanikanth Madabushi	CDER	Katrin Rupalla	PhRMA (J&J)
Janet Maynard	CDER	Derek Scholes	BIO
Jennifer Mercier	CDER	Lucy Vereshchagina	PhRMA
Paul Phillips	CDER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA and Industry discussed progress on the proposals being negotiated. Industry presented proposed revised draft commitment letter language for the Advancing RWE and MIDD proposals. FDA presented proposed revisions to draft commitment letter language for two of the Improve FDA-Sponsor Interactions subproposals regarding FDA providing a rationale for conversion to Written Response Only (WRO) and expanding one of the sections in the PDUFA VII commitment letter to modify FDA's current sponsor reconsideration process. Industry presented proposed

revised draft commitment letter language for the Facilitate First Cycle Reviews labeling subproposal. Industry presented proposed topics for the Facilitate First Cycle Reviews third-party assessment and a response to FDA's counterproposal for prioritized Investigational New Drugs (IND) protocols.

Progress on Proposal Negotiations

FDA and Industry discussed progress on each side's proposals. Industry also agreed to bring ideas on what proposals to prioritize to a future meeting.

Approach to Draft Commitment Letter Language

Industry presented proposed revisions to FDA's Advancing RWE draft commitment letter language. FDA asked clarifying questions about Industry's proposed revisions. Industry agreed to respond to FDA's clarifying questions at a future meeting.

FDA provided an initial response to Industry's proposed MIDD draft commitment letter language revisions. FDA agreed to review the language internally and bring a finalized response to the language at a future meeting.

FDA presented proposed revisions to Industry's draft commitment letter language for two of Industry's Improve FDA-Sponsor Interactions subproposals. The subproposals focus on FDA providing a rationale for converting face-to-face meetings to Written Response Only (WRO) and FDA expanding one of the sections in the PDUFA VII commitment letter for sponsors to request reconsideration for face-to-face meetings.[1] Industry agreed to review FDA's revised draft commitment letter language in more detail and bring a response to a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

Industry presented proposed topics for the Facilitate First Cycle Reviews third-party assessment tentatively agreed to on November 18th, integrating the suggested topics FDA presented at the January 15th meeting. FDA and Industry agreed that both sides should outline the objectives of the third-party assessment. FDA and Industry also agreed to consider what the PDUFA VIII commitment letter should capture regarding the third-party assessment. FDA and Industry will continue discussing the third-party assessment at a future meeting.

Industry stated it is generally aligned with FDA's prioritized IND protocols counterproposal. However, Industry proposed focusing on pivotal protocols in lieu of using the term Phase 3 protocol as a pivotal trial can be a Phase 2b trial or in some rare cases, a Phase 1 trial. The change to focus on pivotal protocols should also be incorporated in reviewer training and in the third-party assessment agreed to on November 18th. Industry agreed that submissions for pivotal protocols would be identified in the cover letter. Industry also agreed that the submissions for pivotal protocols would include the date the planned study was discussed at a milestone meeting (e.g., EOP2 meeting), the planned trial start date, and specific questions about the pivotal

[1] See the January 15th meeting summary for details on FDA's response to Industry's subproposals.

protocol. FDA stated it would discuss Industry's feedback internally and bring a response to a future meeting.

Additionally, Industry presented proposed draft language for its proposal for FDA to provide labeling comments to sponsors at least 2 months before the PDUFA action date. FDA stated it would review the language and respond at a future meeting.

FDA and Industry discussed the scope of Industry's Post-Marketing Requirements (PMR) protocols subproposal which proposes that FDA establish timeframes for review of protocols, interim study deliverables, Statistical Analysis Plans (SAPs), and final reports. After further discussion, FDA stated it would review the PMR protocols proposal internally and bring feedback to a future meeting.

Next Steps

The tentative goals for the next meeting on February 3rd will be to discuss the Rare Disease, Facilitate First Cycle Reviews, and Incorporate Regulatory Science into Regulatory Decision-Making proposals.