

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 8, 2026 | 10:30 am–12:30 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss Industry’s Incorporate Regulatory Science into Regulatory Decision–Making proposal, Industry’s Improve FDA–Sponsor Interactions proposal, FDA’s Meetings Management proposal, and Industry’s Facilitate First Cycle Reviews proposal.

PARTICIPANTS

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

MEETING SUMMARY

FDA and Industry agreed on proposed draft commitment letter language for Drug Development Tools (DDT), including biomarker qualification, and Benefit Risk Assessment. FDA and Industry agreed to continue negotiating a portion of Industry’s Improve FDA–Sponsor Interactions proposal and revert to the current PDUFA VII commitments for FDA’s Meetings Management

proposal. FDA and Industry confirmed the scope of Industry's Facilitate First Cycle Reviews proposal.

Approach to DDT and Benefit Risk Assessment Draft Commitment Letter Language

FDA agreed to Industry's proposed DDT and Benefit Risk Assessment draft commitment letter language. FDA and Industry agreed that the DDT and Benefit Risk Assessment portion of Industry's Incorporate Regulatory Science into Regulatory Decision-Making proposal could be closed out from further negotiations by the premarket subgroup negotiations team.

Approach to Improve FDA-Sponsor Interactions and Meetings Management Proposals

FDA presented a summary of the previous Improve FDA-Sponsor Interactions and Meetings Management negotiation. Industry emphasized the importance of timely FDA-sponsor interactions during drug development and reiterated that it had provided sufficient Full-Time Equivalent (FTE) and resource support over the course of PDUFA. Industry provided feedback on the summary and expressed interest in continuing to discuss its Improve FDA-Sponsor Interactions proposals related to Multi-Division Review (MDR), Face-to-Face to Written Response Only (WRO) conversion justification, and expanding on instances where Industry can request that meetings not be converted to WRO.

Given that FDA and Industry did not align on FDA's Meetings Management proposal, both sides agreed on reverting to the current state of meetings management under PDUFA VII. FDA and Industry agreed to continue discussing instances where MDR could enable more efficiencies in communication and advice to sponsors. FDA noted that sponsors can and already have requested meetings that included representatives from different divisions; however, the manner in which these meetings are requested and the content for discussion might contribute to some requests not being granted while others are.

FDA also raised concerns that an MDR request may require more SMEs than is typical, exacerbating scheduling challenges and contributing to FDA missing its scheduling goals. Industry acknowledged this challenge but stated that MDR might help eliminate redundant meetings thereby helping with the scheduling challenges. Both FDA and Industry agreed that characteristics of a MDR should be identified that can assure consistent consideration and decisions on granting across different divisions, and, if necessary, to allow FDA to schedule outside the current scheduling timeframe for the specific meeting type. FDA stated that it was not interested in a new meeting type and that characteristics of an MDR would need to fit into the current meeting types agreed to in PDUFA VII. FDA stated it would need to have further internal discussions on Industry's two proposals pertaining to WRO and that it would bring a counterproposal to a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

FDA asked for clarification on Industry's current version of its Facilitate First Cycle Reviews proposal. With exception for review of prioritized IND protocols, Industry confirmed that their proposal on tracked metrics to Facilitate First Cycle Reviews¹ included its current ask. FDA presented a proposal to address Information Requests (IRs) occurring after Late Cycle Meetings. FDA agreed to draft language stating that the Agency will include a description of the issue which triggered the IR for the applicant's reference.

FDA concluded by presenting a response to Industry's Third-Party Assessment proposal, noting that Agency generally agrees with the proposal. FDA recommended that both sides prepare and agree on a complete list of topics to be included in the assessment. Industry agreed with FDA's recommendation. Industry asked whether FDA would still respond to Industry's other proposed tracked metrics. FDA and Industry agreed that FDA would provide a response to the other proposed tracked metrics at future meetings.

Next Steps

The tentative goals for the next meeting on January 13th will be to discuss the Advancing Real-World Evidence, Model-Informed Drug Development, and Enhancing Transparency and Consistency Related to Patient Experience Data draft commitment letter language. Additionally, both sides will discuss the Facilitate First Cycle Reviews proposal.

¹ See the December 2nd meeting summary for details. Industry submitted a second revision to its proposal for review of prioritized IND protocols on December 18th.