Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 20, 2026 | 1:00 pm – 3:00 pm

Virtual Format

MEETING PURPOSE

To discuss FDA's Model-Informed Drug Development (MIDD) proposal, Industry's Improve FDA-Sponsor Interactions 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)
Meghana Chalasani	CDER	Steve Berman	BIO
Irene Chan	CDER	Carl Garner	PhRMA (Eli Lilly)
Emily Ewing	CDER	Kelly Goldberg	PhRMA
Andrew Kish	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
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA and Industry discussed the draft commitment letter language for the MIDD proposal. Industry presented its multi-division review meeting proposal. FDA presented its response to Industry's Prioritized Investigational New Drug (IND) Protocols proposal.

Approach to MIDD Draft Commitment Letter Language

FDA presented revised draft commitment letter language for the MIDD proposal. Industry generally agreed with the draft language but expressed concern that FDA's proposed language deviated from precedent in previous commitment letters by acknowledging FDA's goal to hire staff to support MIDD outside of the hiring section of the commitment letter. FDA and Industry discussed addressing this concern in both the Finance subgroup and the Steering Committee.

Approach to Improve FDA-Sponsor Interactions Proposal

Industry presented further detail on its proposal for multi-division review (MDR) meetings, with the stated goal of making FDA-sponsor interactions more streamlined and efficient. Industry proposed to meet this goal by reducing redundant meetings covering identical questions for FDA and Industry and minimizing the potential for divergent feedback from different review divisions. Industry also proposed that sponsors would identify the lead division in the multi-division review meeting request, consistent with current practice, and specify desired FDA attendees. Additionally, Industry stated that relevant FDA guidance documents should be updated to reflect MDR and should outline relevant criteria and the process for making such a request. Industry concluded by presenting further detail on the scope, lead division, timing expectations, potential topics, and meeting types that would apply under multi-division review.

FDA asked which guidance documents Industry envisioned that the Agency would update to include information on MDR meetings. Industry clarified that its intent was to ensure that sponsors know when requesting an MDR is appropriate rather than specifying a particular guidance where this information would be available. FDA also asked how sponsors would identify all the divisions that should be involved in an MDR meeting. Industry responded that sponsors would identify the divisions in the meeting request cover letter. At the end of the discussion, FDA stated it would bring criteria for identifying the divisions involved in MDR and bring a response to the entire proposal at a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

FDA presented a response to Industry's Prioritized IND Protocols proposal. FDA stated that it views timely IND protocol feedback as important and a shared responsibility between the Agency and sponsors. FDA stated that it does not agree with having a tracked metric for reviewing IND protocols. FDA proposed modifications to Industry's definition of pivotal trials. FDA also proposed that sponsors include certain information in their protocol submission to better identify that these are protocols for pivotal trials, intended to provide substantial evidence of effectiveness in marketing applications that FDA can prioritize for review.

FDA noted after an IND is opened, hundreds of supporting documents may be submitted to the IND during its life cycle. FDA stated that the Agency receives over 12,500 new protocols and amendments to INDs annually, along with submissions for meeting requests and various reports. FDA presented data on protocol volume and resource challenges to meeting aspirational timelines listed in internal resources for reviewers. FDA stated that staff capacity limits FDA's ability to meet all aspirational timelines. Additionally, the Agency presented data showing that, of

commercial IND protocol submissions with corresponding communication, more than half received a response before day 60.

FDA concluded with a counterproposal for Industry to document in the cover letter for the protocol submission (1) that the planned study was discussed at a milestone meeting with FDA, (2) the planned trial start date, and (3) critical questions requiring responses to enable trial initiation. FDA proposed tracking review of prioritized IND protocols without implementing performance metrics. FDA also proposed updating internal documents for reviewers and training review staff with an emphasis on review of Phase 3 and/or pivotal protocols. FDA also proposed including IND protocol-related topics in a third-party assessment.

Industry asked about the scope of INDs included in the median time to provide protocol comments data and noted that the inclusion of original IND protocols could affect the median time. FDA stated it would bring the response to a later meeting. Industry also asked about whether the Agency tracks communications with sponsors that state sponsors cannot proceed until comments are provided, citing concerns with the timeliness of the communications. FDA stated that if the Agency suggests sponsors not initiate the trial until FDA comments are received, that is because the Agency wishes to avoid situations in which concerns are not raised until after a pivotal trial is underway.

Industry asked about the updates FDA envisions to internal reviewer trainings. FDA responded that updates to the internal training would be an opportunity for Industry to weigh in with feedback on how the Agency could improve. Industry agreed to review FDA's response in more detail and provide feedback at a future meeting.

Next Steps

The goals for the next meeting on January 22nd will be to discuss the Advancing Real-World Evidence and Enhancing Transparency and Consistency Related to Patient Experience Data draft commitment letter language. Additionally, both sides will discuss the Facilitate First Cycle Reviews and Improve FDA-Sponsor Interactions proposals.