Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 26, 2026 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss the Rare Disease, Improve FDA-Sponsor Interactions, Enhancing Transparency and Consistency Related to Patient Experience Data (PED), and Facilitate First Cycle Reviews proposals.

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
Meghana Chalasani	CDER	Rob Berlin	BIO (Vertex)
Irene Chan	CDER	Steve Berman	BIO
Sonday Kelly	CDER	Carl Garner	PhRMA (Eli Lilly)
Andrew Kish	CDER	Kelly Goldberg	PhRMA
Phillip Kurs	CBER	Kristy Lupejkis	PhRMA
Mark Levenson	CDER	Alison Maloney	PhRMA (Bayer)
Janet Maynard	CDER	Adora Ndu	BIO (Bridge Bio)
Jennifer Mercier	CDER	Drew Sansone	BIO (Alkermes)
Paul Phillips	CDER	Derek Scholes	BIO
John Scott	CBER	Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry reached alignment on the Enhancing Transparency and Consistency Related to PED draft commitment letter language. FDA and Industry agreed to the draft commitment letter language for the Improve FDA-Sponsor Interactions Multi-Divisional Review Meetings (MDM) subproposal. FDA presented draft commitment letter language for the Rare Disease Endpoint Advancement (RDEA) program proposal. Industry proposed additional revisions to the Facilitate First Cycle Reviews pivotal protocols draft commitment letter language.

Approach to Draft Commitment Letter Language

FDA proposed one revision to a portion of the Enhancing Transparency and Consistency Related to PED draft commitment letter language, to which Industry agreed. After further discussion, FDA and Industry reached alignment on Industry's proposed revisions to the Enhancing Transparency and Consistency Related to PED draft commitment letter language.

Industry proposed a revision to the MDM draft commitment letter language, to which FDA agreed. After further discussion, FDA and Industry agreed to the MDM draft commitment letter language.

FDA presented draft commitment letter language for the RDEA proposal, noting differences between the PDUFA VII commitment letter language and the proposed changes for PDUFA VIII. Industry asked an initial clarifying question, which FDA addressed. Industry agreed to review the draft commitment letter language and provide a detailed response in a future meeting.

Industry proposed additional revisions to FDA's pivotal protocols draft commitment letter language. FDA and Industry discussed the revisions, and FDA agreed to provide a response at a future meeting.

Next Steps

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