

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 17, 2026 | 1:00 pm-3:00 pm

Virtual Format

MEETING PURPOSE

To discuss the Enhancing Transparency and Consistency Related to Patient Experience Data (PED) draft commitment letter language and the Improve FDA-Sponsor Interactions proposal.

PARTICIPANTS

FDA

Issam Zineh	CDER
Nana Adjeiwaa-Manu	CDER
Thamar Bailey	CDER
Marie Bradley	CDER
Meghana Chalasani	CDER
Irene Chan	CDER
Emily Ewing	CDER
Andrew Kish	CDER
Mark Levenson	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Amy Comstock Rick	CDER
Katie Rivers	CBER
John Scott	CBER

INDUSTRY

Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Derek Scholes	PhRMA
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry discussed the Enhancing Transparency and Consistency Related to PED draft commitment letter language. FDA presented a response to the Improve FDA-Sponsor Interactions subproposal on Multi-Division Review Meetings (MDR).

Approach to Enhancing Transparency and Consistency Related to PED Draft Commitment Letter Language

Industry proposed revisions to the Enhancing Transparency and Consistency Related to PED draft commitment letter language. FDA asked for clarification on Industry's proposed revisions, which Industry addressed. FDA agreed to review Industry's proposed revisions and propose revised draft commitment letter language in a future meeting.

Approach to Improve FDA-Sponsor Interactions Proposal

FDA presented a response to Industry's Multi-Division Review Meetings (MDR) subproposal.¹ FDA stated that it was generally aligned with Industry's proposal and proposed additional details to clarify meeting scheduling timelines, the information sponsor meeting requests should contain, as well as examples of when MDR meetings would be appropriate. FDA and Industry discussed additional examples of instances where MDR meetings would be useful. Industry agreed to review FDA's feedback and present a response in a future meeting.

Next Steps

The goals for the next meeting on February 19th will be to discuss the Rare Disease, Incorporate Regulatory Science into Regulatory Decision-Making, and Facilitate First Cycle Reviews proposals.

¹ See the January 20th meeting summary for details.