Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 3, 2026 | 1:00 pm–3:00 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss the Advancing Real-World Evidence (RWE), Incorporate Regulatory Science into Regulatory Decision-Making, Facilitate First Cycle Reviews, and Rare Disease proposals.

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
Phillip Kurs	CBER	Alison Maloney	PhRMA (Bayer)
Mark Levenson	CDER	Adora Ndu	BIO (Bridge Bio)
Rajanikanth Madabushi	CDER	Katrin Rupalla	PhRMA (J&J)
Janet Maynard	CDER	Drew Sansone	BIO (Alkermes)
Jennifer Mercier	CDER	Derek Scholes	BIO
Paul Phillips	CDER	Lucy Vereshchagina	PhRMA
Amy Comstock Rick	CDER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA presented proposed revisions to the Advancing RWE draft commitment letter language. Industry proposed draft commitment letter language for FDA to train its review staff on the development, review, and approval of drugs using regulatory science approaches. FDA presented proposed revisions to the Facilitate First Cycle Reviews draft labeling commitment letter language. Industry confirmed the scope of its Facilitate First Cycle Reviews proposal and shared

minor updates to draft commitment letter language for Information Requests (IRs) after Late-Cycle Meetings. Industry presented a response to FDA's Rare Disease Endpoint Advancement (RDEA) counterproposal.

Approach to Draft Commitment Letter Language

FDA presented proposed revisions to the Advancing RWE draft commitment letter language. Industry agreed to review the revisions and provide a response in a future meeting.

Industry presented proposed draft commitment letter language for its Incorporate Regulatory Science into Regulatory Decision-making subproposal. The subproposal suggests that FDA train its review staff on the use of regulatory science tools[1] in the regulatory review and decision-making process. Industry stated this is intended to help transition pilots into practice and facilitate learnings from subject matter experts (SMEs) transferred to reviewers. FDA agreed to review the draft commitment letter language and provide a response in a future meeting.

FDA and Industry agreed to the draft commitment letter language for instances where FDA needs to send Information Requests (IRs) to sponsors after the Late-Cycle Meeting.[2]

FDA presented proposed revisions to the labeling subproposal draft commitment letter language. Industry suggested revisions. FDA agreed to review Industry's feedback and provide a response in a future meeting.

Approach to RDEA Proposal

Industry presented feedback on FDA's counterproposal.[3] Industry asked clarifying questions about the rationale for parts of the counterproposal, including how FDA would plan to implement transitioning RDEA from a pilot to a Type C meeting. FDA briefly responded to Industry's questions and agreed to provide a detailed response in a future meeting.

Next Steps

The goals for the next meeting on February 5th will be to discuss the Improve FDA-Sponsor Interactions, Enhancing Transparency and Consistency Related to Patient Experience Data, and Facilitate First Cycle Reviews proposals.

---

[1] These tools include novel endpoint development, Real-World Evidence (RWE), Drug Development Tools (DDT), including the use of biomarkers, Model-Informed Drug Development (MIDD), Complex Innovative Design (CID), Digital Health Technologies (DHTs), and Selective Safety Data Collection (SSDC).

[2] See the PDUFA VII Commitment Letter, Section I.B.6.e.ii: https://www.fda.gov/media/151712/download?attachment

[3] See the January 27th meeting summary for details on FDA's counterproposal.