Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 10, 2026 | 1:00 pm–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss the Advancing Real-World Evidence (RWE), Incorporate Regulatory Science into Regulatory Decision-Making, Facilitate First Cycle Reviews, and Improve FDA-Sponsor Interactions 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
Marie Bradley	CDER	Rob Berlin	BIO (Vertex)
Meghana Chalasani	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	Katrin Rupalla	PhRMA (J&J)
Paul Phillips	CDER	Drew Sansone	BIO (Alkermes)
Amy Comstock Rick	CDER	Lucy Vereshchagina	PhRMA
Katie Rivers	CBER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA and Industry agreed to the Advancing RWE draft commitment letter language. FDA presented a response to Industry's Incorporate Regulatory Science into Regulatory Decision-Making proposal. FDA and Industry agreed to the Facilitate First Cycle Reviews draft commitment letter language regarding FDA providing labeling comments. Industry presented a response to FDA's counterproposal on posting redacted action packages. FDA proposed revisions

to draft commitment letter language regarding FDA providing a rationale for converting face-to-face sponsor meetings to Written Response Only (WRO).

Approach to Draft Commitment Letter Language

FDA and Industry agreed to the Advancing RWE draft commitment letter language.

FDA proposed revisions to Industry's Incorporate Regulatory Science into Regulatory Decision-Making draft commitment letter language regarding training CDER and CBER review staff on the use of available regulatory science tools[1] in the drug development and regulatory review process. Industry provided an initial response to FDA's revisions and agreed to propose revised draft commitment letter language at a future meeting.

FDA and Industry agreed to the Facilitate First Cycle Reviews draft commitment letter language regarding FDA providing labeling comments.

FDA proposed revisions to the Improve FDA-Sponsor Interactions draft commitment letter language regarding the Agency providing a rationale for converting face-to-face meetings to Written Response Only (WRO). Industry agreed to review the revisions and respond at a future meeting.

Approach to Incorporate Regulatory Science into Regulatory Decision-Making Proposal

FDA responded to Industry's subproposal for the Agency to create a new action package section clarifying what types of sponsor-submitted regulatory science tools were used during the drug's development as well as in the regulatory review process. FDA also responded to Industry's subproposal for the Agency to report aggregate information on the use of regulatory science tools in regulatory decision-making.[2]

In response to both subproposals, FDA stated that the evidence in published research[3] demonstrates that the action package as currently constructed is already transparent. FDA and Industry discussed the Agency's concerns with the additional administrative burden the proposed changes would add for reviewer staff and the potential impact on the Agency's ability to meet review timelines. Industry reiterated its point that it is difficult to understand if and when regulatory science tools were utilized in regulatory decision-making in the action package. It is not clear how the Agency considers the regulatory science tools sponsors submit during the review process and what tools worked and did not work. Industry stated that this information would facilitate drug development and might help to reduce the number of inquiries and meeting

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[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 January 27th meeting summary for details.

[3] https://journals.sagepub.com/doi/abs/10.1177/17407745251415190

requests sponsors submit to FDA. After further discussion, Industry agreed to review FDA's response and provide detailed feedback at a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

Industry presented a counterproposal that the Agency proactively post redacted action packages of priority efficacy supplements within 6 months of approval, as well as a counterproposal to staff resources proposed by FDA. FDA and Industry discussed Industry's rationale for the proposed resources. FDA and Industry also discussed the proposed timeline for posting redacted action packages of priority efficacy supplements. FDA agreed to respond to Industry's counterproposal in detail at a future meeting.

Next Steps

The goals for the next meeting on February 12th will be to discuss the Rare Disease, Improve FDA-Sponsor Interactions, and Facilitate First Cycle Reviews proposals.