



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 22, 2026 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss draft commitment letter language for the Advancing Real-World Evidence (RWE) and Enhancing Transparency and Consistency Related to Patient Experience Data (PED) proposals. To discuss the Improve FDA-Sponsor Interactions and Facilitate First Cycle Reviews proposals.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Nana Adjeiwaa-Manu	CDER
Thamar Bailey	CDER
Marie Bradley	CDER
Meghana Chalasani	CDER
Irene Chan	CDER
Emily Ewing	CDER
Sunday Kelly	CDER
Andrew Kish	CDER
Mark Levenson	CDER
Rajanikanth Madabushi	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Katie Rivers	CBER
John Scott	CBER
Issam Zineh	CDER

INDUSTRY

Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Annetta Beauregard	BIO
Steve Berman	BIO
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Adora Ndu	BIO (Bridge Bio)
Katrin Rupalla	PhRMA (J&J)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry discussed the draft commitment letter language for the Advancing RWE and Enhancing Transparency and Consistency Related to PED proposals. Industry presented a response to FDA’s perspectives on Industry’s Written Response Only (WRO) Proposal. Industry

presented a response to FDA's proposed draft language for Information Requests (IRs) after the Late-Cycle Meeting and FDA's perspectives on Industry's labeling subproposal.

Approach to Advancing RWE Draft Commitment Letter Language

Industry submitted edits to FDA's Advancing RWE draft commitment letter language. FDA responded to Industry's edits and indicated that summarizing RWE for all approvals would be challenging and resource intensive. FDA suggested that summarizing RWE for new indications is likely most useful for stakeholders. Industry asked about the rationale for limiting the summary to new indications. FDA indicated that resources are constrained. Industry stated it would review FDA's proposed revisions in further detail and provide a response at a later meeting.

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

FDA presented revised draft commitment letter language for the Enhancing Transparency and Consistency Related to PED proposal. Industry suggested potential revisions to the draft language FDA presented and agreed that it would be helpful for the Agency to increase awareness of how PED should be submitted but reiterated that Industry's goal is to increase the use of PED for regulatory decision making and PED's reflection in labeling. In its response, FDA highlighted the shared responsibility that sponsors and the Agency have to appropriately use PED in the drug development and regulatory processes, respectively. After further discussion on the draft commitment letter language and the value of PED, Industry stated it would review FDA's proposed revisions in further detail and provide a response at a later meeting.

Approach to Improve FDA-Sponsor Interactions Proposal

Industry presented a response to FDA's January 15th presentation on Written Response Only (WRO) rationales. Specifically, Industry presented draft commitment letter language focused on reconsideration of WRO conversions and sponsors providing justification for a face-to-face meeting.

FDA asked how Industry's response addressed FDA's perspectives presented at the January 15th meeting. Industry suggested that FDA prepare draft commitment letter language with its perspective for discussion. FDA stated that it would review Industry's response in further detail and provide draft commitment letter language at a later meeting.

Approach to Facilitate First Cycle Reviews Proposal

In response to Industry's question from the January 20th meeting about the scope of what is included in the median Investigational New Drug (IND) protocol response timelines, FDA noted that the data it presented excluded 30-day IND reviews and would therefore not skew the data to suggest a shorter review response time.

Given the Agency's presentation on prioritized IND protocols presented at the January 20th meeting, FDA and Industry agreed to discuss Industry's Post-Marketing Requirement (PMR) protocol review timelines subproposal in a future meeting.

Industry presented a response to FDA's draft commitment letter language on Information Requests (IRs) after the late-cycle meeting. Industry agreed to FDA's draft commitment letter language and to incorporating a topic in the third-party assessment on how often late-cycle meetings involve an issue previously identified by FDA and communicated to sponsors either earlier in application review or during the IND stage.

Lastly, Industry expressed concern with FDA's position that the Agency opposes incorporating a tracked metric for labeling comments to be sent sponsors no later than 2 months prior to the PDUFA action date. FDA and Industry agreed to continue discussing Industry's labeling subproposal at a later meeting.

Next Steps

The goals for the next meeting on January 27th will be to discuss Industry's Facilitate First Cycle Reviews proposal, FDA's Rare Disease proposal, and Industry's Incorporate Regulatory Science into Regulatory Decision-Making proposal.