



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 15, 2026 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss draft commitment letter language for Industry’s Enhancing Transparency and Consistency Related to Patient Experience Data (PED) proposal. To discuss FDA’s Rare Disease, Industry’s Improve FDA-Sponsor Interactions, and Industry’s Facilitate First Cycle Reviews proposals.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Emily Ewing	CDER
Thamar Bailey	CDER
Marie Bradley	CDER
Irene Chan	CDER
Kathleen Davies	CDER
Sunday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CDER
Mark Levenson	CDER
Rajanikanth Madabushi	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Amy Comstock Rick	CDER
Katie Rivers	CDER
John Scott	CDER
Issam Zineh	CDER

INDUSTRY

Mark Taisey	BIO (Amgen)
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
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

Industry presented proposed revisions to the draft commitment letter language for the Enhancing Transparency and Consistency Related to PED proposal. Industry presented a

counterproposal to FDA's Rare Disease proposal for the Rare Disease Innovation Hub (the Hub) and Rare Disease Endpoint Advancement (RDEA). FDA presented perspectives on Industry's Facilitate First Cycle Reviews and Improve FDA-Sponsor Interactions proposal.

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

Industry presented proposed revisions to FDA's draft commitment letter language for the Enhancing Transparency and Consistency Related to PED proposal. FDA asked a clarifying question about Industry's proposed revision, which Industry addressed. FDA agreed to review Industry's proposed revisions in further detail and respond at a future meeting.

Approach to Rare Disease Proposal

Industry presented a counterproposal. Industry stated that while programming (i.e. workshops, training, etc.) is important, ensuring that learnings from programming translates to drug development paradigms as well as regulatory decision-making is critical to ensuring that we can collectively serve the needs of patients. Industry stated that it appreciates the Rare Disease Innovation, Science, and Exploration (RISE) workshops conducted to date and supports FDA continuing to conduct RISE workshops (with defined deliverables) under the existing FDA Rare Diseases Program. Industry stated that it does not support referencing the Hub in the commitment letter, given that FDA organizational structure is not typically dictated in the commitment letter.

Industry stated that it is supportive of FDA continuing to convene RISE workshops to facilitate scientific exchange, identify challenges, and promote solutions that support efficient and effective development and review of therapies for rare diseases. Industry stated FDA should focus on barriers to rare disease drug development when organizing each workshop including via public solicitation of topics. Industry proposed that workshops be oriented toward identifying practical solutions to address the specific challenges discussed, and FDA consider key scientific, clinical and regulatory questions that need to be addressed. Additionally, Industry proposed FDA participants include review division subject matter experts (SMEs), leadership, industry representatives, academic experts and other relevant stakeholders to ensure informed and authoritative perspectives. Finally, Industry proposed FDA make a summary of RISE workshop topics and discussions publicly available. Industry also proposed that the Agency use insights from the workshops to identify areas to improve clarity and consistency in the regulatory review process.

FDA asked whether Industry had considered including any resources with its counterproposal. Industry clarified that its counterproposal included the resource ask the Agency provided with their original proposal, for the number of RISE programs included in FDA's original proposal. FDA agreed to consider Industry's RISE workshop counterproposal and bring feedback to a later meeting.

Industry subsequently presented a counterproposal for RDEA, noting that it supported RDEA continuing into PDUFA VIII but wanted to ensure stakeholders can learn from endpoint

development and transition RDEA into ordinary review practice. Industry acknowledged the RDEA pilot program is not ready to be transitioned into ordinary review practice. For these reasons, industry proposed a phased implementation approach modeled after the Model-Informed Drug Development program, with full implementation to occur by the end of PDUFA VIII. As part of the phased implementation approach, Industry proposed that FDA increase the number of eligible proposals accepted on a quarterly basis. As access to the RDEA program increases, FDA will eventually allow sponsors to request a Type C, RDEA-focused meeting at any point during drug development for the purposes of discussing novel endpoints. Industry concluded by proposing that while FDA is still operating under the RDEA pilot program, it will conduct up to three RDEA public workshops by the end of PDUFA VIII, which should be informed by engaging with sponsors and the experience of review divisions.

FDA asked Industry what it would mean for RDEA to become a Type C meeting. Industry clarified that it was proposing that RDEA be a regular Type C meeting focused on novel endpoints. FDA asked whether Industry agreed that the Agency could remove the current disclosure commitment in the PDUFA VII RDEA commitment letter language. Industry agreed with removing the current disclosure commitment in the commitment letter.

Approach to Facilitate First Cycle Reviews Proposal

FDA responded to the questions Industry posed during the January 13th meeting regarding Agency staff workload and the timeframe for posting action packages. Specifically, industry asked if FTEs working on Complete Response Letter (CRL) disclosure are the same as those working on action package disclosure. FDA confirmed the resources are the same for both CBER and CDER. Industry acknowledged FDA's response.

FDA presented draft commitment letter language on including context for Information Requests (IRs) after Late-Cycle Meetings. Industry agreed to review the language and provide a response at a future meeting.

FDA also presented proposed topics to be included in the First Cycle Reviews third-party assessment tentatively agreed to during the November 18th meeting¹. FDA provided a response to Industry's labeling proposal. FDA noted in its presentation that it is not feasible for the Agency to add any new performance goals or specific timelines in this round of user fee negotiations, but FDA would be willing to consider updating commitment letter language to specify that FDA will include a target date for communicating labeling as part of the FDA's filing communication letter. Industry agreed to review FDA's proposed third-party assessment topics and response to the labeling proposal for discussion at a later meeting.

Approach to Improve FDA-Sponsor Interactions Proposal

FDA presented a response to Industry's subproposals on providing a rationale for conversion to Written Response Only (WRO) and expanding one of the sections in the PDUFA VII commitment

¹ See the November 18th meeting summary for more details.

letter to request reconsideration for face-to-face meetings beyond pre-IND meetings. FDA proposed that sponsors should include a rationale in their initial meeting requests for any WRO eligible meeting stating why a face-to-face meeting is necessary in place of the current reconsideration mechanism, to streamline the process and reduce unnecessary delays for both Industry and FDA. FDA stated it was willing to include a rationale in the FDA meeting granted letter explaining why a WRO was granted if sponsor rationale was provided. Industry did not have any immediate questions and agreed to review the counterproposal in more detail.

Next Steps

The goals for the January 20th meeting will be to discuss the draft commitment letter language for FDA's MIDD proposal, discuss Industry's Improve FDA-Sponsor Interactions proposal, and discuss Industry's Facilitate First Cycle Reviews proposal.