



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Premarket Subgroup

February 24, 2026 | 1:00 pm – 3:00 pm

Virtual Format

### MEETING PURPOSE

To discuss the Rare Disease, Improve FDA-Sponsor Interactions, Enhancing Transparency and Consistency Related to Patient Experience Data (PED), 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
Sonday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CBER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Amy Comstock Rick	CDER
Katie Rivers	CBER
John Scott	CBER
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

FDA and Industry agreed to the Rare disease Innovation, Science, and Exploration (RISE) workshops draft commitment letter language. FDA presented draft commitment letter language for the Improve FDA-Sponsor Interactions Multi-Divisional Review Meetings (MDM) subproposal. FDA proposed revisions to the Enhancing Transparency and Consistency Related to

PED draft commitment letter language. Industry proposed revisions to the Facilitate First Cycle Reviews prioritized IND (“pivotal”) protocols draft commitment letter language.<sup>1</sup>

### **Approach to Draft Commitment Letter Language**

FDA and Industry agreed to Industry’s proposed revisions to the RISE Workshops draft commitment letter language.<sup>2</sup>

FDA presented draft commitment letter language for the MDM subproposal. Industry asked clarifying questions about the scope of meetings that would be considered under MDM and about the level of detail in the draft commitment letter language, which FDA addressed. Industry agreed to review FDA’s proposed draft commitment letter language in detail and provide a response in a future meeting.

FDA proposed revisions to the Enhancing Transparency and Consistency Related to PED draft commitment letter language. Industry suggested additional revisions to the draft commitment letter language. Industry agreed to propose further revisions to the draft commitment letter language at a future meeting.

Industry proposed initial revisions to FDA’s pivotal protocols draft commitment letter language. FDA and Industry discussed the revisions, and Industry agreed to propose additional revisions at a future meeting.

### **Approach to Facilitate First Cycle Reviews Proposal**

FDA and Industry agreed that both parties had reached an impasse for the Post-Marketing Requirement (PMR) protocol review timelines subproposal. FDA and Industry agreed to remove the subproposal from negotiations; however, both sides acknowledged the importance of providing timely PMR protocol feedback.

FDA and Industry agreed to pause premarket negotiations on the redacted action packages subproposal until FDA and Industry complete further discussion of proposed resources in the Finance subgroup.

### **Next Steps**

The goals for the next meeting on February 26<sup>th</sup> will be to discuss the Rare Disease, Enhancing Transparency and Consistency Related to Patient Experience Data, Improve FDA-Sponsor Interactions, and Facilitate First Cycle Reviews proposals.

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<sup>1</sup> FDA and Industry agreed to the pivotal protocols proposal at the January 29<sup>th</sup> meeting.

<sup>2</sup> Industry proposed revisions to the RISE workshops draft commitment letter language at the February 19<sup>th</sup> meeting.