Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 12, 2026 | 10:30 am – 12:30 pm

Virtual Format

MEETING PURPOSE

To discuss the Rare Disease, Improve FDA-Sponsor Interactions, and Facilitate First Cycle Reviews 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	Carl Garner	PhRMA (Eli Lilly)
Kathleen Davies	CDER	Kelly Goldberg	PhRMA
Emily Ewing	CDER	Kristy Lupejkis	PhRMA
Sonday Kelly	CDER	Alison Maloney	PhRMA (Bayer)
Andrew Kish	CDER	Adora Ndu	BIO (Bridge Bio)
Mark Levenson	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		
Katie Rivers	CBER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA presented a response to Industry's Rare Disease Endpoint Advancement (RDEA) pilot program feedback and draft commitment letter language for the Agency's Rare Disease Innovation, Science, and Exploration (RISE) workshops. FDA and Industry agreed to draft commitment letter language regarding FDA providing a rationale for converting face-to-face sponsor meetings to Written Response Only (WRO). FDA presented draft commitment letter

language for the Facilitate First Cycle Reviews prioritized IND protocols subproposal. Industry presented a counterproposal for its Facilitate First Cycle Reviews Post-Marketing Requirement (PMR) protocol review timelines subproposal.

Approach to Draft Commitment Letter Language

FDA and Industry agreed to FDA's proposed revisions of the WRO Rationale draft commitment letter language.

FDA presented draft commitment letter language on the prioritized IND protocols subproposal agreed to on January 29th. FDA and Industry discussed Industry's clarifying questions and initial response to the draft commitment letter language. Industry agreed to propose revisions to FDA's draft commitment letter language at a future meeting.

FDA presented draft commitment letter language for the Agency's RISE Workshops. Industry asked clarifying questions about the draft commitment letter language, which FDA addressed. Industry agreed to propose revisions to the draft commitment letter language at a future meeting.

Approach to Rare Disease Proposal

FDA presented an updated counterproposal for the RDEA pilot program. FDA stated it is aligned with the goal of moving RDEA towards Type C, RDEA-focused meetings starting in Fiscal Year (FY) 2030 without a need for a formal assessment to help inform the transition.

FDA and Industry confirmed that once Type C, RDEA-focused meetings were implemented, sponsors would specify that they are interested in an RDEA-focused meeting in their Type C meeting request cover letter. After further discussion, Industry agreed to respond to FDA's counterproposal in detail at a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

Industry presented a counterproposal regarding PMR protocol review timelines. Industry proposed that the Agency complete protocol review and communicate feedback to the sponsor in a consistent timeframe and note the duration of any delayed feedback in its Postmarketing Requirements and Commitments searchable database. FDA stated that there are several reasons a PMR might be delayed beyond the Agency missing a timeline to provide protocol feedback, including challenges sponsors face with study enrollment. After further discussion on the various types of PMRs that exist and other issues, FDA agreed to provide a detailed response in a future meeting.

Next Steps

The goals for the next meeting on February 17th will be to discuss the Improve FDA-Sponsor Interactions and Enhancing Transparency and Consistency Related to Patient Experience Data proposals.