



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 19, 2026 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss the Rare Disease, Incorporate Regulatory Science into Regulatory Decision-Making, 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
Emily Ewing	CDER
Sonday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CBER
Mark Levenson	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Howard Phillips	CDER
Paul Phillips	CDER
Amy Comstock Rick	CDER
Katie Rivers	CBER
Issam Zineh	CDER

INDUSTRY

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

MEETING SUMMARY

FDA and Industry agreed to the Rare Disease Endpoint Advancement (RDEA) proposal. FDA and Industry agreed to draft commitment letter language for FDA to train its review staff on the development, review, and approval of drugs using regulatory science approaches. Industry proposed revisions to the Rare disease Innovation, Science, and Exploration (RISE) Workshops draft commitment letter language. Industry presented perspectives on its Incorporate Regulatory

Science into Regulatory Decision-Making subproposals regarding innovative approaches and performance reporting. FDA presented a counterproposal to Industry's redacted action packages proposal. FDA responded to Industry's counterproposal on Post-Marketing Requirement (PMR) protocol review timelines.

Approach to Draft Commitment Letter Language

FDA and Industry agreed to draft commitment letter language for one of Industry's Incorporate Regulatory Science into Regulatory Decision-Making subproposals. Industry's subproposal focused on FDA training its review staff on the development, review, and approval of drugs using regulatory science approaches. FDA and Industry agreed they would consider the draft commitment letter language on training in context with other training-related sections of the entire PDUFA VIII commitment letter at the end of premarket negotiations.

Industry proposed revisions to the RISE Workshops draft commitment letter language. Industry reiterated the value of the RISE workshops. Industry wants to ensure a strong connection with regulatory decision making throughout drug development reviews. FDA proposed an additional revision to the revised draft commitment letter language Industry shared. Industry agreed to make the revision FDA requested and present the revised draft commitment letter language at a future meeting.

Approach to Rare Disease Proposal

FDA and Industry agreed to the RDEA counterproposal FDA presented at the February 12th meeting. The counterproposal stated that RDEA will move towards Type C, RDEA-focused meetings starting in fiscal year 2030.¹ FDA agreed to draft commitment letter language for the RDEA proposal and present it at a future meeting.

Approach to Incorporate Regulatory Science into Regulatory Decision-Making Proposal

Industry stated it heard the FDA's concerns and would not move forward with its aggregated performance reporting subproposal² and a portion of its action package subproposal.³ The removed portion of the action package subproposal suggested that FDA include a narrative summary in the action package briefly describing the regulatory science tools⁴ that were evaluated in the review of the drug and how they informed the regulatory decision-making process.

Industry clarified that the remaining, revised part of its action package subproposal is a checklist that sponsors would complete to indicate where regulatory science tools were used in their

¹ See the February 12th meeting summary for details.

² See the February 10th meeting summary for details.

³ See the January 27th meeting summary for details on Industry's action package subproposal.

⁴ 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).

submissions. FDA would then use the sponsor-provided checklist to indicate whether the Agency considered the specified regulatory science tools in the regulator review process. Industry stated that this checklist will provide value to sponsors and FDA and cited instances where sponsors were unable to identify that regulatory science tools had or had not been considered in the regulatory review process. Industry stated that it wants to encourage greater use of regulatory science tools, so it is important to see where these tools were or were not used to inform regulatory decision making. FDA and Industry discussed FDA's concerns about whether Industry's proposed solution would address the problem Industry identified, which is to offer transparency with respect to how regulatory science tools are being considered in the regulatory review process. FDA agreed to review Industry's proposal in detail and provide a response in a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

FDA presented a counterproposal stating that FDA would proactively post redacted action packages for priority efficacy supplements 12 months after the approval date and a phased in approach over PDUFA VIII. FDA presented an accompanying staff resource request. Industry and FDA discussed the rationale for FDA's resource request and proposed redaction timeline. After further discussion, Industry agreed to review FDA's proposal and provide a detailed response in a future meeting.

FDA responded to Industry's PMR protocol review timelines counterproposal, which included a description in the searchable database for duration of delay when FDA missed a timeline for protocol feedback.⁵ FDA stated that it did not accept Industry's proposal because the proposed language placed a delayed PMR as being solely on FDA even though there are many reasons a final protocol PMR milestone may be delayed, including FDA and sponsors being unable to reach agreement on draft protocols. FDA presented redacted examples of PMRs that included explanations of delayed status which are based on information provided by sponsors in their annual status report. FDA concluded that the Agency's current processes, which are built for the four different types of PMRs, as required under statute or regulations, address Industry's primary concern about the optics of a delayed PMR.

Next Steps

The tentative goals for the next meeting on February 24th will be to discuss the Improve FDA-Sponsor Interactions, Enhancing Transparency and Consistency Related to Patient Experience Data, and Facilitate First Cycle Reviews proposals.

⁵ See the February 12th meeting summary for details.