Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

January 27, 2026 | 1:00 pm–3:00 pm

Virtual Format

MEETING PURPOSE

To discuss the Facilitate First Cycle Reviews, Incorporate Regulatory Science into Regulatory Decision-Making, and Rare Disease 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	Steve Berman	BIO
Irene Chan	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)
Rajanikanth Madabushi	CDER	Drew Sansone	BIO (Alkermes)
Janet Maynard	CDER	Derek Scholes	BIO
Jennifer Mercier	CDER	Lucy Vereshchagina	PhRMA
Paul Phillips	CDER		
Amy Comstock Rick	CDER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

Industry responded to FDA's counterproposal regarding posting all approved redacted action packages. Industry proposed adding a new section on the use of regulatory science tools in the drug development and regulatory review process to FDA's action package. Industry also presented a proposal on FDA performance reporting. FDA presented responses to Industry's

counterproposal for Rare disease Innovation, Science, and Exploration (RISE) workshops and the Rare Disease Endpoint Advancement (RDEA) pilot.

Approach to Facilitate First Cycle Reviews Proposal

Industry sees value in transparency and publication of Action Packages for approved applications including efficacy supplements. Industry understood the Agency's resource concern. Therefore, industry presented a counterproposal for FDA to prioritize publishing all Action Packages for approved redacted priority efficacy supplements within 6 months of the approval date. Industry also proposed that the Agency publish approved standard efficacy supplements within 12 months of the approval date. Industry noted that its original proposal was for all approved action packages (i.e., PDUFA New Molecular Entity (NME) and non-NME New Drug Applications (NDAs), Biologics License Applications (BLAs), and NDA/BLA efficacy supplements) to be published within 30 calendar days of approval.

FDA and Industry discussed Industry's rationale for the counterproposal and resources needed for FDA to implement the counterproposal. Industry confirmed it is not looking for performance goal metrics and would like to track this deliverable in the third party assessment. FDA agreed to review the counterproposal internally and bring a response to a later meeting.

Approach to Incorporate Regulatory Science into Regulatory Decision-Making Proposal

Industry's proposal suggested the Agency create a new section of its action package that would clarify and increase transparency about what types of sponsor-submitted regulatory science tools[1] were used during the drug's development and in the regulatory review process. Industry proposed that the new section include a checklist the Agency would complete to indicate where regulatory science tools were discussed in the action package. Additionally, the section would include a narrative summary briefly describing the types of tools evaluated in the regulatory decision, and FDA's assessment of how and why the data gathered using these approaches informed regulatory decision making. FDA agreed to review the proposal in more detail and provide a response at a future meeting.

Lastly, Industry presented a proposal for FDA to report aggregate information on the use of regulatory science tools in regulatory decision making, with the stated goal of allowing sponsors to glean actionable insights from prior submissions that inform and facilitate future use of these tools. FDA agreed to review the proposal in more detail and provide a response at a future meeting.

[1] 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).

Approach to Rare Disease Proposal

FDA accepted Industry's counterproposal for the Agency to continue the RISE workshops in the PDUFA VIII commitment letter.[2] FDA and Industry agreed that continuing the RISE workshops would require resources. FDA and Industry agreed to move discussion of resources to the finance subgroup. FDA and Industry also agreed not to move forward with FDA's Rare Disease Feedback Meetings[3] proposal.

Industry asked for FDA's feedback on how learnings from the RISE workshops translate to prescription drug review. Industry reiterated that the value of the RISE workshops is ensuring the learnings are incorporated into regulatory decision making across review divisions, citing the considerations it had included in its counterproposal. FDA stated that it would draft commitment letter language with Industry's considerations in mind. Industry confirmed the commitment letter should outline the RISE workshops but not the Hub.

FDA presented a response to Industry's RDEA counterproposal, noting that the Agency was aligned on the value of RDEA and transitioning the meetings included in the pilot to Type C meetings. FDA proposed that background packages be submitted at the time of the meeting request, suggested modifying the number of RDEA meetings offered per accepted proposal, and provided additional suggestions for implementation. Industry stated it would provide further feedback at a future meeting.

Next Steps

The goals for the next meeting on January 29th will be to discuss progress on proposal negotiations along with the draft commitment letter language for Model-Informed Drug Development (MIDD) and Advancing Real-World Evidence (RWE). FDA and Industry will also discuss the Facilitate First Cycle Reviews proposal.

[2] See the January 15th meeting summary for details on Industry's rare disease counterproposals.

[3] See the November 13th meeting summary for details.