Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

March 12, 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		INDUSTRY	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Donna Boyce	PhRMA (Pfizer)
Thamar Bailey	CDER	Annetta Beauregard	BIO
Meghana Chalasani	CDER	Steve Berman	BIO
Irene Chan	CDER	Rob Berlin	BIO (Vertex)
Emily Ewing	CDER	Kelly Goldberg	PhRMA
Sonday Kelly	CDER	Kristy Lupejkis	PhRMA
Andrew Kish	CDER	Alison Maloney	PhRMA (Bayer)
Phillip Kurs	CBER	Adora Ndu	BIO (Bridge Bio)
Janet Maynard	CDER	Katrin Rupalla	PhRMA (J&J)
Jennifer Mercier	CDER	Drew Sansone	BIO (Alkermes)
Paul Phillips	CDER	Derek Scholes	BIO
Katie Rivers	CBER	Lucy Vereshchagina	PhRMA
John Scott	CBER		

MEETING SUMMARY

FDA presented a response to Industry's proposed revisions for the Rare Disease Endpoint Advancement (RDEA) program draft commitment letter language. Industry proposed revisions to FDA's Incorporate Regulatory Science into Regulatory Decision-Making regulatory science workshop draft commitment letter language. FDA presented draft commitment letter language for the third-party assessment.

Approach to Draft Commitment Letter Language

FDA generally aligned with Industry's proposed revisions to the RDEA draft commitment letter language. FDA proposed two revisions to the RDEA draft commitment letter language for Industry's consideration. Industry agreed to review the draft commitment letter language and provide a response at the next meeting.

FDA presented draft commitment letter language for the third-party assessment agreed to on November 18th. FDA proposed conducting two assessments. One assessment would aim to quantify review outcomes and reasons for Complete Responses (CRs) while the other would assess the effectiveness of enhancements to formal meetings being introduced in PDUFA VIII. Industry agreed to review the draft commitment letter language and provide a response at the next meeting.

Approach to Incorporate Regulatory Science into Regulatory Decision-Making Proposal

Industry proposed revisions to FDA's regulatory science public workshop counterproposal presented at the March 5th meeting.[1] Revisions included addition of an opening statement and expectations of outcomes from the workshop. In the proposed language, Industry stated that over the past three PDUFA cycles, resources have been provided to enhance the use of innovative approaches and tools in regulatory decision-making. Industry stated that Industry and FDA must seek additional ways to increase transparency to facilitate shared learning that will strengthen sponsor submissions and encourage consistency and predictability in FDA review.

While FDA proposed publishing a summary report or transcript of the public workshop, Industry proposed that FDA focus on publishing a summary report of the public workshop because a transcript of discussion only is not useful. Industry suggested that the summary report include actionable recommendations for enhancing Industry and FDA communication practices to promote the use of innovative approaches and tools in regulatory decision-making. Industry also proposed that FDA respond to the findings in the report within 12 months of the public workshop and prioritize implementing the actionable recommendations.

FDA expressed concerns with Industry's opening paragraph in the draft commitment letter as FDA felt it portrayed regulatory science and decision tools as resulting entirely from PDUFA programs even though some were initiated by FDA years before being incorporated into PDUFA. FDA suggested replacing Industry's opening with an introductory statement regarding the purpose of using regulatory science tools and objectives of the workshop. FDA also noted that since the public workshop had not been held, it would be difficult to commit to acting on any outputs from the workshop.

Industry stated that it aimed to capture resources and commitments dedicated to regulatory science throughout multiple PDUFA cycles in its proposed revisions and wanted to ensure there was accountability for the resources Industry provided for PDUFA-related regulatory science

[1] See the March 5th meeting summary for details on FDA's counterproposal.

programs. While investment in regulatory science is important, FDA reiterated that not all uses in marketing applications were deemed fit-for-purpose. Industry responded that making progress is critical for regulatory science as significant PDUFA funds have been committed, but progress is not always clear and the intent is to carry through to actualize use of these approaches, when appropriate. Industry expressed concerns with the utility of holding a workshop without also identifying actionable recommendations and a related implementation timeline. To mitigate FDA's concerns, Industry offered building in flexibility to allow FDA to self-prioritize actionable recommendations as part of the post-workshop follow-up. FDA stated that it understood Industry's position about resources committed and agreed to review Industry's response in detail and propose revisions ahead of the next meeting.

Next Steps

The tentative goals for the next meeting on March 19th will be to discuss the Rare Disease, Incorporate Regulatory Science into Regulatory Decision-Making, and Facilitate First Cycle Reviews proposals.