



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

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

Virtual Format

MEETING PURPOSE

To discuss the draft commitment letter language for the 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
Meghana Chalasani	CDER
Irene Chan	CDER
Emily Ewing	CDER
Sonday Kelly	CDER
Andrew Kish	CDER
Mark Levenson	CDER
Phillip Kurs	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Katie Rivers	CDER
John Scott	CDER

INDUSTRY

Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Annetta Beauregard	BIO
Steve Berman	BIO
Rob Berlin	BIO (Vertex)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

Industry proposed revisions to the Incorporate Regulatory Science into Regulatory Decision-Making stakeholder engagement workshop draft commitment letter language. Industry proposed revisions to the draft commitment letter language for the third-party assessments agreed to on November 18th. FDA and Industry discussed a section of the full draft commitment letter.

Approach to Draft Commitment Letter Language

Industry proposed revisions to FDA's revised draft commitment letter language for the stakeholder engagement workshop. Industry's revisions focused on FDA prioritizing implementation of actionable recommendations from the workshop. Industry stated that it wanted to use the stakeholder engagement workshop to help stakeholders understand how using innovative approaches adds value to the drug development process and regulatory decision making. FDA noted that since the public workshop had not been held, it would be difficult to commit to acting on any outputs from the stakeholder engagement workshop. FDA agreed to review Industry's proposed changes and share revised draft commitment letter language in a future meeting.

Industry proposed revisions to the third-party assessments draft commitment letter language centered around providing additional detail and context about the goals and outcomes of the assessment. FDA and Industry discussed the revisions. FDA agreed to provide a response in a future meeting.

FDA and Industry discussed FDA's proposed removal of the Enhanced Communication subsection of the draft commitment letter. FDA and Industry agreed that Industry would discuss the financial implications of removing the subsection in the Finance subgroup.

Next Steps

The tentative goals for the next meeting on March 24th will be to discuss the draft commitment letter language for the Incorporate Regulatory Science into Regulatory Decision-Making and Facilitate First Cycle Reviews proposals. FDA and Industry will also discuss premarket-related sections of the draft commitment letter.