Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

March 24, 2026 | 1:00 pm–3:00 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		INDUSTRY	
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Annetta Beauregard	BIO
Thamar Bailey	CDER	Steve Berman	BIO
Meghana Chalasani	CDER	Rob Berlin	BIO (Vertex)
Irene Chan	CDER	Kristy Lupejkis	PhRMA
Emily Ewing	CDER	Alison Maloney	PhRMA (Bayer)
Sonday Kelly	CBER	Adora Ndu	BIO (Bridge Bio)
Andrew Kish	CDER	Katrin Rupalla	PhRMA (J&J)
Mark Levenson	CDER	Drew Sansone	BIO (Alkermes)
Paul Phillips	CDER	Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry reached alignment on 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 FDA's proposed revisions to selected premarket sections of the draft commitment letter.

Approach to Draft Commitment Letter Language

Industry accepted FDA's proposed revisions to the draft commitment letter language for the stakeholder engagement workshop. Industry proposed an additional revision to the draft commitment letter language, to which FDA agreed. After FDA included Industry's revision, both parties reached alignment on the relevant draft commitment letter language. FDA and Industry also discussed the proposed location for the stakeholder engagement workshop draft

commitment letter language. FDA agreed to share its proposed location in the context of the full draft commitment letter for Industry's consideration prior to the next meeting.

Industry proposed high-level revisions to the third-party assessments draft commitment letter language centered around the goals and outcomes of the assessment. FDA and Industry discussed the revisions. Industry agreed to provide detailed revisions at the next meeting.

Industry aligned with FDA's proposed revisions to the draft commitment letter sections for Review Performance Goals, Program for Enhanced Review Transparency and Communication for NME NDAs and Original BLAs, as well as New Molecular Entity (NME) Milestones and Postmarketing Requirements (PMRs). Industry also aligned with removing the section centered on the Split Real Time Application Review (STAR) Pilot Program, given that both FDA and Industry agreed to discontinue the pilot program on November 20th.

FDA and Industry discussed the Expedited Reviews, Regulatory Decision Tools to Support Drug Development and Review, and Enhancing Regulatory Science and Expediting Drug Development sections of the draft commitment letter. Industry suggested maintaining the title of the Expedited Reviews section for clarity. Industry aligned with most of the proposed revisions in the Enhancing Regulatory Science and Expediting Drug Development section. Industry aligned with all the proposed revisions in the Regulatory Decision Tools to Support Drug Development and Review section. Industry suggested combining the sections focused on regulatory science and decision tools to streamline the draft commitment letter, to which FDA agreed.

Next Steps

The goals for the final meeting on March 26th will be to discuss the draft commitment letter language for the Facilitate First Cycle Reviews proposal. FDA and Industry will also discuss the remaining premarket-related sections of the draft commitment letter.