



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

March 26, 2026 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss the remaining premarket sections of the draft commitment letter. To discuss the draft commitment letter language for the Facilitate First Cycle Reviews proposal.

PARTICIPANTS

FDA

Issam Zineh	CDER
Nana Adjeiwaa-Manu	CDER
Thamar Bailey	CDER
Meghana Chalasani	CDER
Irene Chan	CDER
Emily Ewing	CDER
Sunday Kelly	CDER
Andrew Kish	CDER
Mark Levenson	CDER
Paul Phillips	CDER

INDUSTRY

Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Steve Berman	BIO
Rob Berlin	BIO (Vertex)
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry reached alignment on 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

FDA and Industry aligned on the third-party assessments draft commitment letter language. FDA accepted Industry’s proposed revisions to the draft commitment letter language for the third-party assessments. Industry proposed an additional revision, to which FDA agreed. FDA and Industry aligned on the locations of the third-party assessments draft commitment letter language. Lastly, FDA agreed to share the finalized draft commitment letter language with Industry.

Industry aligned with FDA's proposed revisions to the draft commitment letter sections focused on Review of Proprietary Names to Reduce Medication Errors, Major Dispute Resolution, Clinical Holds, Special Protocol Question Assessment and Agreement, and Pivotal Protocol Prioritization¹. Industry proposed a revision to the Meeting Management Goals section.

FDA and Industry discussed the Enhancing Regulatory Science and Expediting Drug Development as well as the Enhancing Regulatory Decision Tools to Support Drug Development and Review sections FDA combined and revised. Industry agreed to review FDA's proposed revisions and combined sections. After further discussion, FDA also agreed to propose additional revisions to the Enhancing Regulatory Science and Expediting Drug Development section for Industry's consideration after the meeting.

Next Steps

The FDA-Industry premarket subgroup will finalize changes to the premarket sections of the draft commitment letter.

¹ This section refers to the prioritized IND (pivotal) protocols proposal draft commitment letter language agreed to on January 29th.