Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

April 2, 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		INDUSTRY	
Paul Phillips	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Donna Boyce	PhRMA (Pfizer)
Nana Adjeiwaa-Manu	CDER	Annetta Beauregard	BIO
Thamar Bailey	CDER	Steve Berman	BIO
Irene Chan	CDER	Kelly Goldberg	PhRMA
Emily Ewing	CBER	Alison Maloney	PhRMA (Bayer)
Andrew Kish	CDER	Adora Ndu	BIO (Bridge Bio)
		Drew Sansone	BIO (Alkermes)
		Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry tentatively agreed on a revision to the regulatory science tools section[1] of the draft commitment letter. FDA and Industry also discussed PDUFA VII implementation of best practices for FDA and sponsor communication.

Approach to Draft Commitment Letter Language

FDA and Industry discussed revising a sentence at the beginning of the draft commitment letter's regulatory science tools section. Industry proposed revisions. After further discussion, FDA and Industry tentatively agreed on the location and draft language in the sentence. Both parties agreed to review the sentence internally and share feedback after the meeting.

[1] See the March 26th meeting summary for more information on the now-combined regulatory science tools sections.

Next Steps

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