



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

February 5, 2026 | 10:30 am-12:30 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To discuss the Enhancing Transparency and Consistency Related to Patient Experience Data (PED), Improve FDA-Sponsor Interactions, and Facilitate First Cycle Reviews proposals.

PARTICIPANTS

FDA

Mary Thanh Hai	CDER
Nana Adjeiwaa-Manu	CDER
Marie Bradley	CDER
Meghana Chalasani	CDER
Irene Chan	CDER
Emily Ewing	CDER
Sonday Kelly	CDER
Andrew Kish	CDER
Phillip Kurs	CBER
Mark Levenson	CDER
Rajanikanth Madabushi	CDER
Janet Maynard	CDER
Jennifer Mercier	CDER
Paul Phillips	CDER
Amy Comstock Rick	CDER
John Scott	CBER
Issam Zineh	CDER

INDUSTRY

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

MEETING SUMMARY

FDA presented proposed revisions to the Enhancing Transparency and Consistency Related to PED proposal draft commitment letter language. Industry presented proposed revisions to the Written Response Only (WRO) draft commitment letter language regarding FDA providing a rationale for converting face-to-face meetings to Written Response Only (WRO). FDA presented responses to Industry’s Post-Marketing Requirement (PMR) protocol review timelines and redacted action packages subproposals.

Approach to Draft Commitment Letter Language

FDA presented proposed revisions to the Enhancing Transparency and Consistency Related to PED draft commitment letter language. Industry suggested alternate revisions for FDA's consideration. FDA and Industry agreed to separately propose additional revisions to the draft commitment letter language and present their responses in a future meeting.

Industry presented proposed draft commitment letter language revisions regarding its Improve FDA-Sponsor Interactions subproposals for FDA to provide a rationale for conversion to Written Response Only (WRO). FDA agreed to review the draft commitment letter language and present its position in a future meeting.

FDA proposed revisions to the Facilitate First Cycle Reviews draft commitment letter language regarding FDA providing labeling comments. Industry agreed to confirm its position on the proposed draft commitment letter language in a future meeting.

Approach to Facilitate First Cycle Reviews Proposal

FDA presented its response to Industry's PMR protocol review timelines proposal, stating that it could not accept Industry's proposal in its entirety because FDA already has recommended timelines for review of PMR protocols, there is a mechanism to explain the reason for a delayed PMR status on the Agency's public database, and regulations link delayed status to original milestone dates. Industry reiterated concerns around receiving delayed PMR comments from the Agency, which affects sponsor development programs. Industry stated that it would review FDA's proposal and provide a response at a future meeting.

FDA responded to Industry's counterproposal that FDA proactively post all redacted action packages of standard efficacy supplements within 12 months of the approval date and priority efficacy supplements within 6 months of the approval date. FDA proposed that the Agency would proactively prioritize posting redacted action packages for priority efficacy supplements 12 months from the approval date over the course of PDUFA VIII based on data it presented on CDER and CBER's efficacy supplement workload.

Industry asked clarifying questions about the data FDA presented, the staff who currently redact action packages, and the resources needed for FDA's counterproposal. FDA responded to Industry's questions. Industry agreed to review FDA's counterproposal and provide a response in a future meeting.

Lastly, FDA and Industry agreed to prepare objectives for the third-party assessment agreed to on November 18th and discuss them at a future meeting.

Next Steps

The goals for the next meeting on February 10th will be to discuss the Incorporate Regulatory Science into Regulatory Decision-Making, Facilitate First Cycle Reviews, and Improve FDA-Sponsor Interactions proposals.