Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-Market Subgroup

November 6, 2025 | 10:30 am-12:30 pm

FDA White Oak Campus, Silver Spring, MD

MEETING PURPOSE

To address clarifying questions about FDA and Industry pre-market review process enhancement proposals and begin preparing a schedule for discussing proposal topics.

PARTICIPANTS

FDA		Industry	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Nana Adjeiwaa-Manu	CDER	Donna Boyce	PhRMA (Pfizer)
Marie Bradley	CDER	Annetta Beauregard	BIO
Meghana Chalasani	CDER	Rob Berlin	BIO (Vertex)
Irene Chan	CDER	Steve Berman	BIO
Kathleen Davies	CDER	Carl Garner	PhRMA (Eli Lilly)
Emily Ewing	CDER	Kelly Goldberg	PhRMA
Sonday Kelly	CBER	Kristy Lupejkis	PhRMA
Andrew Kish	CDER	Alison Maloney	PhRMA (Bayer)
Mark Levenson	CDER	Adora Ndu	BIO (Bridge Bio)
Rajanikanth Madabushi	CDER	Katrin Rupalla	PhRMA (J&J)
Janet Maynard	CDER	Drew Sansone	BIO (Alkermes)
Jennifer Mercier	CDER	Derek Scholes	BIO
Paul Phillips	CDER	Lucy Vereshchagina	PhRMA
Amy Comstock Rick	CDER		
Katie Rivers	CBER		
John Scott	CBER		

MEETING SUMMARY

During this meeting, FDA asked clarifying questions about Industry's proposal topics. FDA and Industry agreed that FDA will present their detailed proposals at the next meeting. Industry agreed to ask further questions about FDA proposals during the next week's meeting. FDA and Industry began prioritizing the order of proposal topics they would discuss during the

negotiations process. At the end of the meeting, FDA and Industry agreed to review each other's proposals in more detail and discuss them at the next meeting.

Clarifying Questions on Proposals

FDA and Industry discussed FDA's clarifying questions on proposals Industry presented at the previous meeting. The questions asked for further clarification on the problems with first cycle review Industry identified and on their proposed approach to improving this process. FDA also asked for clarification on the transparency requested in the use of Patient Experience Data in the review process. Additionally, FDA asked for clarification on how Industry proposed to translate learnings from pilots under previous PDUFA cycles into practice. Lastly, FDA asked about the intended outcomes for the meeting management changes Industry proposed. Industry agreed to take the questions back and answer them at the next week's meeting.

Schedule of Proposal Topic Discussions

FDA and Industry discussed a proposed schedule for discussing proposal topics. FDA and Industry agreed on which proposals to discuss in more detail in the next week's meeting.

Next Steps

The goals for the next meeting on November 13th will be to continue asking detailed clarifying questions about FDA and Industry proposals and to confirm the schedule for negotiation of proposals.