Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-Market Subgroup

November 4, 2025 | 1:00 pm–3:00 pm

FDA White Oak Campus, Silver Spring, MD & Virtual Format

MEETING PURPOSE

To introduce and address clarifying questions about FDA and Industry pre-market review process enhancement proposals.

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)
Janet Maynard	CDER	Katrin Rupalla	PhRMA (J&J)
Jennifer Mercier	CDER	Drew Sansone	BIO (Alkermes)
Paul Phillips	CDER	Derek Scholes	BIO
Amy Comstock Rick	CDER	Lucy Vereshchagina	PhRMA
Katie Rivers	CBER		
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

The meeting was focused on FDA and Industry's proposal presentations and discussion of initial clarifying questions about each side's proposals. After Industry presented their proposals, FDA asked clarifying questions. FDA then presented their proposals and Industry asked clarifying questions. At the end of the meeting, FDA and Industry began outlining what topics would be out of scope for negotiations by this subgroup and should be referred to other subgroups. Lastly, FDA

and Industry agreed to debrief separately to discuss the proposals that had been presented and prioritize the order of proposals to be negotiated.

Ground Rules

FDA and Industry affirmed the ground rules governing PDUFA VIII reauthorization negotiations.

Industry Pre-Market Proposal Presentation

Industry presented their key proposals, with the goal of enhancing and streamlining the review and meetings management processes for PDUFA VIII. Industry's proposal topic areas are: (1) Facilitate First Cycle Reviews; (2) Incorporate Regulatory Science into Regulatory Decision-Making; (3) Improve FDA-Sponsor Interactions; and (4) Enhancing Transparency and Consistency Related to Patient Experience Data in Regulatory Decision Making.

For the Facilitate First Cycle Reviews proposal, Industry proposed a set of nine enhancements to the regulatory review process to meet original "program" goals of enhanced review. The goal of these enhancements is to improve the clarity and transparency of FDA review of sponsor submissions and FDA-sponsor communications. In the Incorporate Regulatory Science into Regulatory Decision-Making proposal, Industry proposed that learnings from regulatory pilots be incorporated in a standardized way across FDA reviews. Thirdly, in the Improve FDA-Sponsor Interactions proposal, Industry proposed improvements to FDA's meeting request and Written Response Only (WRO) processes. Lastly, in the Enhancing Transparency and Consistency Related to Patient Experience Data in Regulatory Decision Making proposal, Industry proposes more clarity in how patient experience data is used during the review process.

After Industry's presentation, there were clarifying questions from FDA to better understand the proposals Industry had presented.

FDA Pre-Market Proposal Presentation

FDA presented summaries of their key proposal topics, with the goal of enhancing and streamlining the review and meetings management processes for PDUFA VIII. FDA's proposal interest areas are: (1) Advancing Real-World Evidence Program; (2) Complex Innovative Designs (CID); (3) Model-Informed Drug Development (MIDD); (4) Streamlining Review of Certain Efficacy Supplements; (5) Split Real-Time Application Review (STAR) Pilot Program; (6) Meetings Management; and (7) Rare Disease. After FDA's presentation, there were clarifying questions from Industry to better understand the proposals FDA had presented.

For the Advancing Real-World Evidence Program, FDA proposes to maintain the Advancing Real World Evidence pilot with slight adjustments to the eligibility criteria. Additionally, FDA proposes to streamline the CID and MIDD program processes with the stated goal of expanding their benefits to more sponsors. FDA also proposes to streamline the review of certain efficacy

supplements with the goal of improving efficiency in the review process while providing sponsors with greater transparency and predictability. Further, FDA proposes to phase out the STAR Pilot Program and apply learnings to other initiatives. The FDA Meetings Management proposal is intended to simplify the meeting management program, facilitate FDA feedback, and allow or better scheduling efficiency. Lastly, in the Rare Disease proposal, FDA explained its goals of enhance connections within FDA as well as between FDA and external stakeholders and to accelerate the rare disease product development process.

Next Steps

The goals for the next meeting on November 6th will be to continue asking clarifying questions about FDA and Industry proposals to reach a full understanding and for each side to propose a negotiations schedule.