Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Pre-Market Subgroup

November 20, 2025 | 10:30am–12:30pm

Virtual Format

MEETING PURPOSE

To discuss FDA and Industry's detailed proposals for PDUFA VIII.

PARTICIPANTS

FDA		INDUSTRY	
Mary Thanh Hai	CDER	Mark Taisey	BIO (Amgen)
Marie Bradley	CDER	Donna Boyce	PhRMA (Pfizer)
Meghana Chalasani	CDER	Annetta Beauregard	BIO
Irene Chan	CDER	Rob Berlin	BIO (Vertex)
Kathleen Davies	CDER	Steve Berman	BIO
Emily Ewing	CDER	Carl Garner	PhRMA (Eli Lilly)
Sonday Kelly	CBER	Kelly Goldberg	PhRMA
Andrew Kish	CDER	Kristy Lupejkis	PhRMA
Phillip Kurs	CBER	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	Lucy Vereshchagina	PhRMA
John Scott	CBER		

MEETING SUMMARY

FDA and Industry achieved alignment on the Split Real Time Application Review (STAR) pilot program and tentative alignment on the Complex Innovative Designs (CID) program. FDA and Industry then discussed Industry's proposal to Improve FDA-Sponsor Interactions and FDA's Meetings Management proposal. Before wrapping up, FDA and Industry also discussed Industry's proposal to Incorporate Regulatory Science in Regulatory Decision-Making.

Approach to Split Real Time Application Review (STAR) Pilot Program

FDA and Industry agreed to discontinue the STAR pilot program at the conclusion of PDUFA VII, due to limited engagement in the pilot despite FDA's efforts to increase engagement. Industry noted that they do find value in real-time review efforts (like the Real-Time Oncology Review (RTOR) program), and FDA and Industry should continue to engage on how to leverage real-time review to accelerate the availability of products. FDA agreed to engage in those discussions. FDA would like to understand what about STAR did not work and will follow up, as relevant, outside of PDUFA negotiations. FDA and Industry agreed that the Finance subgroup will discuss management of resources allocated to the STAR pilot under PDUFA VII.

Approach to Complex Innovative Designs (CID) Program

FDA reviewed the Agency's proposal to embed the CID program into FDA's existing formal meeting structure, which includes removing the quarterly submission deadlines and disclosure requirements. FDA noted that the Agency is not requesting additional resources to expand the availability of the CID program. FDA indicated CBER and CDER will ensure the subject matter experts and management needed to provide best/consistent advice will be present to discuss CID in existing meeting structure. Industry asked clarifying questions about how the transition would be operationalized, including how subject matter experts would be involved in CID meetings under PDUFA VIII and how the lessons learned from the CID program under previous PDUFA cycles would be disseminated to review staff.

Industry stated that FDA's proposal aligns with their goal to transition pilots and programs initiated in previous PDUFA cycles to regular practice under the PDUFA program. Industry agreed to confirm their alignment with FDA's proposal in a subsequent meeting.

Discussion of Industry Proposal: Improve FDA-Sponsor Interactions and FDA Proposal: Meetings Management

FDA asked Industry questions about their proposal to Improve FDA-Sponsor Interactions. FDA's questions focused on use cases for a proposed multidisciplinary meeting and Industry's suggestions for how a multidisciplinary meeting would be requested and organized.

Industry asked FDA questions about their Meetings Management proposal, which includes extending the timelines associated with the formal meeting types and requesting meeting packages sooner. Industry inquired about the overall purpose and intent of the Meetings Management proposal and its implications for the existing meeting types. As part of the discussion, FDA noted that the percent of meeting requests denied over the last three years has not exceeded five percent. FDA also clarified the purpose of FDA's Enhanced Communication Team.

Industry raised concerns about the "white space" between the time they request the meeting and the time the meeting is scheduled. Should background packages be submitted with the meeting request for all meeting types, the "white space" would be time that Industry cannot move forward on their program. FDA also noted that the Agency has concerns with "white space" from when the meeting is requested, and the review team must wait for the complete background package to begin preparation for some meeting types. The 20 to 30 days that FDA has to wait for the complete background package could be used to not only prepare for the meeting but to also determine needed expertise external to the review team to facilitate scheduling. Industry stressed that the meeting request information already includes questions to FDA and a list of requested experts that should be helpful in facilitating scheduling. FDA and Industry agreed that they share a goal to minimize the "white space" after a sponsor requests a meeting. FDA and Industry agreed to continue to discuss the proposal and how to minimize Industry and FDA "white space."

Industry noted their goal to reduce the proportion of meeting requests converted to Written Response Only (WRO). FDA noted that the Agency does not have the resources to schedule every meeting that industry requests and stated that it would be helpful to specify the characteristics of requests that would provide the most value if responded to via a meeting rather than a WRO.

Lastly, Industry asked clarifying questions about FDA's proposal to streamline meeting types, particularly Type C Surrogate Endpoint (SE) meetings. FDA clarified that the Agency would continue to entertain Type C SE-related questions. Additionally, FDA noted that the Agency's proposal is for Type C SE meeting requests to come in with all Type C meetings.

Industry agreed to discuss FDA's Meetings Management proposal at a later meeting considering the clarifications FDA provided.

Discussion of Industry Proposal: Incorporate Regulatory Science in Regulatory Decision Making

FDA asked Industry about how Industry envisions that FDA incorporate learnings into standard review practice for PDUFA pilots and programs related to regulatory decision tools. Industry clarified that learnings can be incorporated, for example, through MAPPs, SOPPs, guidances, and staff training, with the goal of sharing how learnings were applied for regulatory decision making, which could also be reflected in approval packages. FDA cautioned against a standard approach for all programs and emphasized that each program has unique considerations based on the program's maturity, scale, and purpose. Industry maintained their position that all the pilots and programs be transitioned into regular review practice and noted that continuing programs that, from Industry's perspective, despite commitments over multiple PDUFA cycles, have had limited adoption by review divisions, would have limited return on investment. FDA reminded Industry that the list of "pilots to programs" proposed includes only two that are pilots. These two (RDEA and Advancing RWE) were introduced under PDUFA VII and have had limited

experience to transition to routine review practice. FDA and Industry acknowledged that additional discussion will be needed but that there is alignment on the importance of advancing regulatory decision tools.

Next Steps

The goals for the next meeting on November 25th will be to revisit Industry's position on FDA's CID proposal and to negotiate FDA's Advancing Real-World Evidence Pilot Program proposal