Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

November 18, 2025 | 1:00 pm–3:00 pm

Virtual Format

MEETING PURPOSE

To finish discussing Industry's questions about FDA's detailed proposals and negotiate Industry's Facilitate First Cycle Review proposal.

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)
Phillip Kurs	CBER	Adora Ndu	BIO (Bridge Bio)
Mark Levenson	CDER	Katrin Rupalla	PhRMA (J&J)
Janet Maynard	CDER	Drew Sansone	BIO (Alkermes)
Jennifer Mercier	CDER	Lucy Vereshchagina	PhRMA
John Scott	CBER		
Issam Zineh	CDER		

MEETING SUMMARY

FDA and Industry discussed Industry's remaining questions about FDA's Meetings Management and Rare Disease proposals. Afterward, FDA and Industry began negotiating Industry's Facilitate First-Cycle Review proposal.

Industry Questions on FDA's Meetings Management and Rare Disease Proposals

In FDA's Meetings Management proposal, the Agency proposed updating scheduling goals to account for FDA reviewer workload and signatory capacity. Industry asked questions about ensuring that meeting scheduling is not further delayed based on FDA's proposed updates to scheduling goals. Additionally, Industry asked how changes to meeting request timelines would impact meeting performance goals. Further, Industry asked about FDA's rationale for updating scheduling goals. Lastly, Industry asked about staff dedicated to enhanced communications and for metrics on meetings FDA has denied by meeting type.

For the Rare Disease proposal, Industry asked how the Rare Disease Innovation Hub (the Hub) would help support better integration of rare disease experts into review teams and if all rare disease programs are centralized through the Hub. FDA clarified that the rare disease team is already integrated in the review teams and that the Hub is helping to connect CDER, CBER, and external stakeholders and is not involved in product reviews. Industry also asked if the Rare Disease Endpoint Advancement (RDEA) pilot would continue, as well as about its output thus far. Additionally, Industry asked about what kind of external feedback FDA is seeking through the Hub.

Approach to Industry's Facilitate First Cycle Review Proposal

FDA presented the Agency's positions on each of Industry's Facilitate First Cycle Review subproposals: (1) First Cycle Review Interim Review Metrics; (2) Third-Party Assessment of CDER/CBER Application Review; (3) Investigational New Drugs (INDs) Protocol Submissions; (4) Modify Pre-NDA/BLA Meeting; (5) Day 74-Letter; (6) Mid- and Late-Cycle Meeting and Communications; (7) Completing Inspections; (8) InterCenter Consultative Review (ICCR) Process for Combination Products; and (9) Publishing/Sharing of Reviews (Enhanced Transparency).

During FDA and Industry's negotiation of the First Cycle Interim Review Metrics proposal, FDA presented the position that they do not anticipate accepting or creating new performance metrics. Industry asked about the rationale for not accepting reporting out of additional metrics as the relevant timelines are already included in FDA's Manuals of Policies and Procedures (MaPPs) and Standard Operating Procedures and Policies (SOPPs) and presented the position that they want to address delays in first cycle review and approvals. FDA indicated interim milestones are established as a guide which FDA generally follows but interim milestones are not metrics and are intended to allow for flexibility from application to application based on specific circumstances. FDA and Industry will continue negotiating this subproposal in future meetings.

In their negotiation of the Third-Party Assessment, FDA and Industry tentatively agreed to an assessment focused on the reasons for Complete Response (CR) letters, the factors driving them, as well as what drives extensions in first cycle review timelines, pending further discussion.

FDA and Industry agreed that IND Protocol Submissions are a pain point for both sides, but FDA and Industry do not align on the approach for addressing the problem. When asked to explain how protocol review timelines impact the first cycle approval rate, Industry provided examples where FDA comments on the protocol are not received until long after pivotal trials have already initiated. Industry also noted late feedback on formulation bridging trials and postmarket requirement protocols. FDA noted that not all protocols require FDA feedback and that it has published guidances to support protocol development. FDA and Industry agreed to continue negotiating this subproposal in future meetings.

FDA and Industry reaffirmed that the Modify Pre-NDA/BLA meeting subproposal would be negotiated by the CMC manufacturing subgroup. However, the premarket subgroup will negotiate any Good Clinical Practice (GCP)-related matters.

FDA and Industry agreed that inspections-related matters in the Day 74 Letter subproposal would be negotiated by the CMC manufacturing subgroup. Additionally, FDA and Industry discussed Industry's concerns with receiving late inter-Center consults. Industry also expressed interest in knowing from which other Centers consults have been requested. FDA and Industry will continue negotiating this subproposal in future meetings. However, both sides agreed to include a study of whether late consults contribute to CRs in the Third-Party assessment.

FDA and Industry discussed Industry's concerns about receiving late Information Requests (IRs), and Industry presented the position that they observe late IRs often lead to clock extensions in the first cycle and CR letters. Industry also agreed to present experiences on problems with attendance at mid- and late-cycle meetings at a subsequent meeting. FDA and Industry will continue negotiating the Mid-and-Late Cycle Meeting and Communications subproposal in future meetings.

Afterward, FDA and Industry discussed Industry's Inter-Center Consultative Review (ICCR) Process for Combination Products subproposal. Industry presented the position that they want to ensure that PDUFA dates are met for ICCRs and had experienced that some ICCRs are late. FDA and Industry will continue negotiating the ICCR subproposal in future meetings.

FDA and Industry reaffirmed that Industry's Completing Inspections subproposal would be negotiated by the CMC manufacturing subgroup.

Lastly, FDA and Industry discussed Industry's Publishing/Sharing of Reviews (Enhanced Transparency) subproposal, which requests that FDA post redacted action packages of all approved PDUFA NDAs, BLAs, and efficacy supplements. FDA noted that redacted action packages for NME NDAs and BLAs are posted approximately 4 to 6 weeks post approval and explained that the Agency prioritizes these postings before non-NME NDAs. FDA explained that approval packages for efficacy supplements are not posted as part of routine practice due to the notably higher volume of action packages, far exceeding NME NDAs/BLAs and non-NMEs, combined.

FDA noted its position that resource constraints would prohibit FDA from posting redacted action packages of all approved PDUFA NDAs, BLAs, and efficacy supplements. FDA also noted that Industry could submit a Freedom of Information Act (FOIA) request for redacted action packages of approved efficacy supplements. Industry presented the position that there is interest in making data on all action packages available to increase learnings on FDA regulatory decisions. FDA noted Industry and the public could also learn from CR information in action packages . FDA and Industry will continue negotiating the Publishing/Sharing of Reviews (Enhanced Transparency) subproposal in future meetings.

Next Steps

The goals for the next meeting on November 20th will be to agree to an approach to FDA's Split Real-Time Application Review (STAR) Pilot Program and negotiate FDA's Complex Innovative Designs (CID), FDA's Meeting Management, as well as Industry's Improve FDA-Sponsor Interactions proposals.