Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Premarket Subgroup

December 18, 2025 | 10:30 am-12:30 pm

Virtual Format

MEETING PURPOSE

To discuss negotiations progress thus far and finalize the Complex Innovative Design (CID) commitment letter language. To discuss Industry's perspective on Industry's Improve FDA-Sponsor Interactions and FDA's Meetings Management proposals.

PARTICIPANTS

FDA	
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INDUSTRY	
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Donna Boyce	PhRMA (Pfizer)
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
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

MEETING SUMMARY

FDA and Industry discussed progress on negotiating each side's proposals thus far. FDA and Industry aligned on the final draft commitment letter language for CID. Industry presented a response to FDA's revised Meetings Management proposal and to FDA's perspectives on Industry's Improve FDA-Sponsor Interactions proposal.

Negotiations Progress Discussion

FDA and Industry reviewed the progress of each side's proposals[1] in detail. FDA and Industry agreed to remove FDA's Streamlining Review of Certain Efficacy Supplements proposal from further negotiations. FDA stated that the Agency already has authority under Section 3031 of the 21st Century Cures Act to streamline review of efficacy supplements that meet specified criteria. Industry agreed with FDA's statement and expressed that it encourages FDA to continue exploring how to better leverage its authority under Section 3031. FDA agreed with Industry's position, noting that in bringing up this proposal for negotiations, there will be more FDA and external awareness of the Agency's authority under Section 3031. Industry agreed to present a response to FDA's rare disease proposal in January 2026.

FDA and Industry discussed progress on the nine subproposals[2] within Industry's Facilitate First Cycle Reviews proposal. FDA presented data in previous meetings that countered Industry's premise that there are increasing Complete Response Letter (CRL) rates. FDA stated that work can be done that will be beneficial to stakeholders, Industry, the public, and the Agency. FDA noted that both sides are continuing to negotiate seven of the Industry subproposals and presented progress on them (First Cycle Review Interim Review Metrics, Third Party Assessment, IND Protocols, Day 74 Letter, Mid- and Late-Cycle Meeting and Communications, InterCenter Consultative Review Process for Combination Products, and Publishing/Sharing of Reviews – Enhanced Transparency). FDA presented the position that it viewed Industry's subproposal for the Agency to post redacted action packages for all PDUFA NDAs (NME and non-NME), BLAs, and efficacy supplements as out of the scope of Industry's overall proposal to facilitate first cycle reviews. Furthermore, this subproposal is resource intensive. FDA noted that Industry can obtain redacted reviews through a Freedom of Information Act (FOIA) request. FDA stated that the third-party assessment Industry proposed can serve as an avenue for learning how both FDA and Industry can improve in their transparency. FDA reaffirmed that two of the subproposals (Modify Pre-NDA/BLA Meeting and Completing Inspections) will be discussed in the Chemistry, Manufacturing, and Controls (CMC) subgroup.

Industry stated that it was not aligned with FDA's position on Industry's proposal to post redacted action packages for all PDUFA NDAs, BLAs, and efficacy supplements. Industry expressed that it does not see FOIA requests for efficacy supplements as sufficient, and that Agency responses to Industry's first FOIA requests takes years. FDA reiterated that Industry's ask was extensive. Industry requested data on metrics for FOIA requests, the number of FOIA staff, and whether FOIA staff are meeting expected timelines. Industry stated that it would be helpful for the requests to be expedited. FDA noted that negative consequences are high for the Agency

[1] See the November 4th, November 6th, and November 13th meeting summaries for details on FDA and Industry's proposals.

[2] See the November 18th meeting summary for details.

and sponsor if the Agency does not correctly redact action packages. FDA requested that Industry consider making changes to its Enhanced Transparency subproposal.

FDA and Industry discussed which proposals FDA and Industry can reach alignment on in January and which proposals will require more time to negotiate. FDA expressed that both sides had made substantial progress on their approach to regulatory science pilots and programs for PDUFA VIII. FDA stated that both sides might be able to finish negotiating their approach to most regulatory science pilots and programs in January 2026. Industry agreed with FDA's statement. FDA suggested that both sides consider areas where they can meet halfway for proposals that will take longer to negotiate. FDA and Industry agreed to consider the progress of each proposal as negotiations continue.

Approach to CID Commitment Letter Language

FDA presented its response to Industry's proposed changes to FDA's CID commitment letter language. Industry agreed with FDA's response. FDA and Industry aligned on the finalized draft CID commitment letter language. FDA agreed to revise the commitment letter language to reflect FDA and Industry's discussion and share the finalized draft language with Industry.

Industry Response to Meetings Management Proposal

Industry presented responses to FDA's Meetings Management proposal.[3] Industry expressed that it understood FDA wanted more time to review sponsor meeting packages. Industry heard FDA's proposal that if sponsors sent meeting packages three and five additional days sooner than the current timeline for Type C and Type B meetings, respectively, it would allow more time for the FDA to schedule. Industry and FDA discussed the Agency's proposal to issue responses to meeting requests for all meeting types sooner. Industry rejected FDA's revised scheduling window as it would delay Sponsor/FDA interactions beyond current, funded PDUFA performance metrics. Industry countered with a new scheduling timeline for Type C and B meetings by shifting meeting scheduling timelines earlier by three and five days for these two meeting categories.

FDA asked for clarification on how Industry's proposal will address the Agency's volume of meeting requests presenting challenges to scheduling and sufficient time to review the background package for meeting types that often have complex programs if the Agency has less time to schedule a sponsor meeting. Industry clarified that sponsors would need to provide their background package earlier and that regardless of when the meeting is scheduled, FDA would have more time to review the package. FDA asked if Industry wanted to remove consideration of FDA's proposal that Industry could choose to revert to PDUFA VII scheduling goals if FDA

[3] See the December 16th meeting summary for details on the revised proposal FDA presented.

scheduled more than half of meetings (excluding Type A) in the last 5 days of the scheduling window. Industry opted to focus on areas where it would receive earlier responses from the FDA.

FDA asked if Industry would consider an FDA proposal to have a narrower scheduling window for sponsor meetings. Alternately, in exchange for FDA's scheduling window proposal, Industry could receive preliminary responses a few days sooner. Industry emphasized that it is most critical for sponsors to receive responses from the FDA as soon as possible and did not agree with the above suggestions.

Industry Response to FDA Perspectives on Improve FDA-Sponsor Interactions Proposal

Industry stated that the goal of its multi-division review (MDR) proposal is to make FDA-sponsor interactions more streamlined and efficient, noting that it is a way to reduce redundant meetings covering identical questions for FDA and Industry. Industry stated that the MDR could apply to single Investigational New Drugs (INDs) with multiple indications and multiple INDs for the same product for separate indications when a common issue affects development or review across multiple divisions. Industry also stated that the MDR could be applied to Type B End-of-Phase and Type C meetings.

FDA stated that what Industry proposed is currently possible and asked if Industry is bringing multiple meeting requests to multiple divisions. Industry responded that sponsors have done so, citing that some sponsors have sent one letter across multiple divisions and had their meeting requests granted, while others who have done so have had their meeting requests denied. FDA asked whether Industry was running into pain points using this approach. Industry responded that formalizing the approach would help sponsors have MDRs in a consistent way when necessary. FDA stated that it would consider Industry's proposal.

Industry acknowledged FDA's responses to Industry's Written Response Only (WRO) proposal.[4] Additionally, Industry proposed language on sponsor follow-up opportunities with the FDA, which it stated was consistent with recent Agency announcements of a pilot and updates to relevant Standard Operating Procedures and Policies (SOPPs). FDA corrected Industry's proposed language that is included in the cover letter issued with final meeting minutes, which states FDA will strive to respond to a clarification question specific to one discipline. Industry acknowledged FDA's correction to the proposed language Industry presented.

Industry presented its response to FDA's comments on Industry's proposal that the Agency provide a detailed written rationale to sponsors at the time of meeting type conversion to ensure the conversion is consistent with PDUFA commitments. Industry stated that a request for the wrong meeting type wastes resources for both FDA and Industry. Industry asked how FDA proposes providing more education to sponsors on the appropriate criteria for Type D meetings as opposed to other meeting types. Industry stated that sponsors are uncertain regarding the

[4] See the December 16th meeting summary for details.

acceptance criteria for Type D meetings. Industry concluded by stating that it remains interested in greater transparency on the rationale for converting Type D meeting requests to Type C.

FDA asked for examples of meetings incorrectly being converted from Type D to Type C, presenting the position that FDA has tried to provide examples of Type D meetings through the public comments and online. FDA asked if there was a different issue that would help the Agency identify the disconnect sponsors are experiencing. Industry agreed to share examples of meetings that have incorrectly been converted from Type D to Type C at a subsequent meeting.

Approach to Meetings Management and Improve FDA-Sponsor Interactions Proposals

After further consideration, FDA stated that Industry's adjustments to FDA's proposal would not address FDA's key challenges as stated at the onset of negotiations, which included its ability to achieve meeting scheduling goals. FDA presented the position that both sides likely have unique pain points and collective challenges, and that the major issue that FDA is trying to resolve in its Meetings Management proposal (i.e., managing the increasing volume of meeting requests against limited signatory staff capacity required to attend sponsor meetings) does not appear to be feasible with Industry's counterproposal. FDA stated that the changes Industry presented would not serve either side well and suggested maintaining the current meeting commitments under PDUFA VII.

Industry asked clarifying questions about whether FDA wanted to resolve the issue of not having enough time to review background packages, stating that it has funded significant Full-Time Equivalent (FTE) resources for meetings management, which did not appear to help the issue. FDA stated both sides recognized that meeting scheduling is a problem and an issue that impacts Industry. FDA acknowledged that while the additional resources have been helpful, the challenge with scheduling meetings is that there are a fixed number of signatories and a fixed number of hours available for scheduling an increasing volume of meetings. FDA stated that the Agency was trying to address this issue in PDUFA VIII with a scheduling window, and that Industry's proposal would worsen FDA's challenges with scheduling, which would not serve either side well. Industry also asked if FDA's position applied to Industry's counterproposal on WROs and its proposed language on clarification of meeting minutes. FDA stated that its position to maintain the current meeting goals under PDUFA VII referred to all aspects of each side's meetings-related proposals.

Next Steps

The goals for the next meeting on January 6th will be to discuss FDA's Advancing Real-World Evidence proposal, FDA's Rare Disease proposal, and Industry's Incorporate Regulatory Science into Regulatory Decision-Making proposal.