



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

December 18, 2025 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To report on the second stakeholder consultation meeting, discuss Industry’s feedback on FDA’s proposals, and share updates from the subgroups.

PARTICIPANTS

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai	CDER
Amy Ramanadham	CDER
Larry Lee	CDER
Josh Barton	CDER
Sonday Kelly	CBER
Christine Hunt	OCC
Kate Greenwood	OCC

INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Adora Ndu	BIO (Bridge Bio)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)

MEETING SUMMARY

FDA summarized for Industry the second stakeholder consultation meeting, held on December 5th. Following the summary, FDA and Industry briefly discussed the status of the Information Technology (IT) and Cell and Gene Therapy (CGT) proposals. The FDA and Industry subgroup leads provided summaries of their subgroup’s accomplishments from this week and their plans for January.

Stakeholder Meeting Summary

FDA shared that FDA held its second meeting with registered patient and consumer groups on December 5th, 2025. FDA presented on six regulatory science pilots and programs included in PDUFA VII and heard questions and feedback from meeting participants on each pilot or program.

FDA highlighted that participants were generally aware of the pilots and programs prior to the meeting and that participants voiced broad support for most of the pilots and programs. FDA shared that some participants voiced concern with innovative methods replacing randomized control trials, especially for products in the accelerated approval pathway, and participants strongly supported rigorous standards and transparency around the use of innovative methods (e.g., model-informed drug development, complex innovative trial designs, real-world evidence). Other participants acknowledged that these methods have been essential in specific therapeutic areas.

FDA noted that participants also strongly supported the Rare Disease Endpoint Advancement (RDEA) pilot program. FDA shared that participants expressed demand for endpoint development and public engagement around product approval and that participants also advocated for additional resources to support demand for this pilot program. Similarly, FDA shared that participants supported the Biomarker Qualification Program (BQP) but expressed concern about long timelines.

Finally, FDA reported that participants had mixed reviews of the Split Real Time Application Review (STAR) pilot program, with some disappointed by the lack of industry participation in the pilot. FDA noted that some participants inquired about reasons for the lack of industry participation.

FDA noted that at least one subgroup already used feedback from this stakeholder meeting to inform their discussions.

Approach to Information Technology (IT) and Cell and Gene Therapy (CGT)

FDA acknowledged that Industry provided a counterproposal in response to FDA's proposed approach to the IT section of the PDUFA VIII commitment letter. FDA noted that the Industry counterproposal includes additional components and that FDA will consult with internal experts and provide a response to Industry's counterproposal in January.

Industry shared that they plan to send FDA a counterproposal in response to FDA's proposed approach to the CGT section of the PDUFA VIII commitment letter. Industry noted that they are generally aligned with FDA's approach. Industry emphasized that resources were provided in PDUFA VII and it is important to understand current FDA staffing. Industry wants to ensure that learnings from the PDUFA VII commitments related to CGT are disseminated and applied moving forward. Industry emphasized that their intent is to ensure guidance informs reviews. Industry also highlighted the importance of appropriate FDA staffing to support CGT product review.

Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Post-Market Safety; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups, as well as the Steering Committee, summarized their accomplishments and plans for next steps. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Wrap Up

FDA and Industry acknowledged the intense amount of effort required to conduct these negotiations. FDA thanked the negotiating teams for their professionalism and commitment to data-driven discussions. FDA and Industry will reconvene in January to continue negotiations.