



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

January 22, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To report on the January stakeholder consultation meeting 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
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)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA summarized for Industry the third stakeholder consultation meeting, held on January 9th. The FDA and Industry subgroup leads also provided summaries of their subgroup's accomplishments from this week.

Stakeholder Meeting Summary

FDA shared that FDA held its third meeting with registered patient and consumer groups on January 9th, 2026. FDA presented on Patient-Focused Drug Development (PFDD), post-market safety (including the Sentinel Initiative, Risk Evaluation and Mitigation Strategies (REMS), and

Post-Marketing Requirements (PMRs)), and orphan drug fee exemptions and exceptions. FDA heard questions and feedback from meeting participants on each topic.¹

FDA highlighted that participants strongly support PFDD for elevating the patient voice and systematically integrating patient experience data into drug development. FDA also shared that participants raised concerns about conflicts of interest in patient experience studies, the weight of patient experience data in approvals, and endpoint validation. FDA noted that participants advocated for resources to support PFDD and treatment of PFDD as a core design principle in drug development.

Across post-market safety topics, FDA shared that participants pressed for transparency in regulatory processes and public access to post-market safety data. FDA also shared that participants supported Sentinel's role in post-market safety surveillance and patient engagement. FDA noted that participants raised concerns about actionable outputs of Sentinel analyses, PDUFA funding priorities, and limited data transparency and access. FDA also noted that stakeholders requested clearer criteria for use of the Active Postmarket Risk Identification and Analysis (ARIA) System, versus PMRs, and potential integration with FDA's Adverse Event Reporting System (FAERS) dashboard capabilities.

FDA shared that participants acknowledged FDA's efforts to strengthen REMS assessments amid rising submissions. FDA reported that participants raised concerns about transparency, drivers of increases in REMS methodologies submissions, feasibility of REMS in ultra-rare diseases, impacts of draft safety labeling guidance, and conflicts of interest in sponsor-led evaluations.

FDA reported receiving limited feedback on PMRs but shared participant concerns about long and opaque PMR timelines and the need for clearer scientific justification, adherence to post-market commitments, and broader use of PMRs.

FDA reported that many stakeholders suggested they need more time to consider FDA's proposal to assess fees for supplements seeking to add non-orphan indications to products approved for orphan indications. FDA shared that of those who provided feedback during the meeting, many advocated for maintaining incentives for rare disease drug development and expressed reservations about the proposal. FDA noted that some participants felt the proposal may increase administrative burden for FDA and could discourage innovation and investment in rare disease drug development. FDA reported that a few stakeholders were supportive of FDA's proposal, requested broader transparency regarding the orphan drug indication program, and suggested that FDA should also consider removing previously granted market exclusivity.

Industry asked clarifying questions about the feedback FDA shared, which FDA responded to.

¹ *These minutes provide a summary of the stakeholder feedback that FDA reported to Industry. Please see the 1/9/2026 minutes for "Stakeholder Discussions on Reauthorization" for more details.*

Subgroup Progress Updates

Industry raised a concern that although the Finance subgroup is assuming FDA will be staffed in PDUFA VIII to the capacity funded by PDUFA VII, other FDA subgroups may be negotiating without that assumption and instead negotiating based on current resource constraints. FDA committed to discussing this concern with the FDA subgroup negotiating teams.

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. FDA reported that the Nonprescription Drug Products subgroup concluded their active negotiations. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

The goals for the next meeting on January 29th will be to revisit FDA's America First proposals, discuss how hiring needs will be represented in the commitment letter, and share progress updates from the subgroups.