



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

February 12, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To discuss FDA’s America First and orphan drug fee proposals, share a summary of the February stakeholder 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
Issam Zineh	CDER
Sonday Kelly	CBER
Christine Hunt	OCC
Kate Greenwood	OCC

**These participants departed after the orphan drug fee proposal discussion.*

INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Adora Ndu	BIO (Bridge Bio)
Drew Sansone	BIO (Alkermes)
Derek Scholes	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Lucy Vereshchagina	PhRMA
Glen Murphy*	CHPA (Kenvue)
Carolyn Herrmann*	CHPA
Marcia Howard*	CHPA
David Spangler*	CHPA
Erin Oliver*	CHPA (Haleon)

MEETING SUMMARY

FDA provided updates on FDA’s America First proposals, and Industry shared questions and concerns. FDA then shared feedback from the stakeholder consultation meeting held on February 2nd. The FDA and Industry subgroup leads provided summaries of their subgroup’s accomplishments from this week.

America First Proposals

FDA shared that FDA's proposal to limit the small business waiver to applicants based in the United States (U.S.) remains a priority for the Agency. FDA also shared a revised fee incentives proposal, in which sponsors of applications that anchor their Phase 1 clinical development in the U.S. pay a reduced fee for a new drug application (NDA) or biologics licensing application (BLA). FDA confirmed that, in this revised proposal, there are no fees levied during the investigational new drug (IND) stage.

Industry reiterated their concerns that PDUFA may not be the most appropriate mechanism for incentivizing clinical development in the U.S. Industry also noted that they still have questions about the feasibility, practicality, and potential unintended consequences of FDA's revised proposal. Industry then shared an extensive list of questions about the revised proposal, including questions about which applications would be eligible for the reduced fee and how FDA would confirm eligibility, amount of the fee differential and how the fee amounts would be determined, expected impact of the fee differential on clinical development in the U.S., and what statutory changes would be needed to implement the fee differential. Industry highlighted concerns about the amount of the fee differential and FDA's justification for that differential. Industry questioned whether FDA considered whether a large fee differential could be considered a tax rather than a user fee. Industry also expressed concern that, in the case of acquisitions, the company submitting an application (and paying the fee) may not have had control over where the clinical trials were conducted. Industry requested confirmation that the fee differential would only apply to applications for which the first in human studies were initiated in PDUFA VIII (i.e., on or after October 1, 2027). FDA acknowledged Industry's questions and agreed to respond at a future meeting.

Orphan Drug Fee Exception/Exemption Proposal

FDA shared that FDA's proposal to assess a fee for the first supplement seeking to add a non-orphan indication to a product approved for an orphan indication remains a priority for the Agency. Industry expressed concerns that this proposal may disincentivize companies from exploring broader therapeutic utility of drugs, especially for non-orphan but limited populations. Industry noted this proposal may conflict with Congressional support for rare disease drug development incentives and certainly conflicts with some of the feedback FDA has heard from the patient advocacy community in the stakeholder meetings. Industry also posed questions about how FDA would avoid disincentivizing research and whether FDA anticipates concerns from Congressional staff. FDA acknowledged Industry's questions and agreed to respond at a future meeting.

Stakeholder Meeting Summary

FDA shared that the Agency held a stakeholder consultation meeting on February 2nd to present and hear feedback on the Rare Disease Innovation Hub ("the Hub"), first cycle review outcomes,

and PDUFA resourcing and finances.¹ FDA reported that patient and consumer representatives supported the Hub and emphasized the importance of stakeholder engagement with FDA and streamlined pathways for engagement. FDA also reported that meeting participants expressed concern about the sufficiency of resources allocated to the Hub and interest in how the Hub will work with FDA's rare disease teams and help disseminate knowledge to reviewers.

FDA shared that participants were interested in learning more about first cycle review outcomes and PDUFA staffing. FDA noted that participants appreciated FDA sharing information about first cycle review outcomes and expressed interest in more granular data about review outcomes. FDA also noted that participants expressed support for sufficient FDA staff and concern that staff reductions, leadership involvement in reviews, and expanded use of expedited pathways are eroding trust in FDA's review standards. FDA reported that participants supported additional resources to manage the additional workload associated with reviewing complex methods.

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. FDA and Industry agreed that clarification is needed about the resources agreed to for Post-Market Safety commitments. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

FDA and Industry agreed to revisit the America First proposals next week.

¹ *These minutes provide a summary of the stakeholder feedback that FDA reported to Industry. Please see the 2/2/2026 minutes for "Stakeholder Discussions on Reauthorization" for more details.*