



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

February 26, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To discuss an Industry counterproposal to FDA's America First fee incentives proposal and to 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)
Lucy Vereshchagina	PhRMA
Glen Murphy*	CHPA (Kenvue)
Carolyn Herrmann*	CHPA
Marcia Howard*	CHPA
David Spangler*	CHPA
Erin Oliver*	CHPA (Haleon)

**These participants departed after the America First discussion.*

MEETING SUMMARY

Industry shared a counterproposal to FDA's America First fee incentives proposal, and FDA asked clarifying questions. The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week.

America First Fee Incentives Proposal

Industry reiterated their concerns with the fee differential proposed in FDA's America First fee incentives proposal. Industry stated the FDA's proposed three-time fee differential would be excessively punitive rather than an incentive for substantial changes to development decisions. Industry also acknowledged FDA's statement at a previous meeting that the proposed fixed fees would require changes to the existing 80/20 financial structure. Industry stated their belief that this proposal would negatively impact the broader financial structure of the PDUFA program. Industry then proposed that the fee for applications submitted in PDUFA VIII where the Phase 1 trials were initiated on or after October 1st, 2027, and where the eligibility criteria for initiating the Phase 1 trials in the United States were met, would be half of the full application fee. Industry shared that this approach would be feasible to implement and provide an incentive while avoiding unnecessary punitive measures for programs in which initiating trials in the United States may not be feasible. Industry also noted that this approach aligns with the existing fee structure, in which applications without clinical data also pay half of the full application fee.

Industry also proposed that FDA and Industry discuss process improvements that incentivize companies to conduct their clinical trials in the United States by streamlining the review of investigational new drug applications (INDs). FDA indicated that FDA's proposal is only related to financial incentives and that FDA is unlikely to consider process improvements beyond the topics already under consideration by the Pre-Market Subgroup. Industry agreed to provide specific suggestions for process improvements.

FDA agreed to consider Industry's counterproposal.

Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups, as well as the Steering Committee, summarized their accomplishments and plans for next steps. The FDA and Industry Finance subgroup leads acknowledged disagreements in the Finance subgroup about the use of PDUFA funds. FDA and Industry restated their commitment to reaching an agreement. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

FDA and Industry agreed to continue discussing FDA's America First proposals and the non-orphan indication supplement fee proposal at upcoming meetings.