



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Steering Committee

February 19, 2026 | 3:30pm – 5:00pm

Virtual Format

### MEETING PURPOSE

To respond to Industry questions about FDA’s proposals related to America First and supplements for non-orphan indications 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
Issam Zineh	CDER
Sonday Kelly	CBER
Kate Greenwood	OCC

#### INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Adora Ndu	BIO (Bridge Bio)
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

FDA responded to questions posed by Industry at previous meetings, regarding FDA’s America First proposals and non-orphan indication supplement fee proposal. The FDA and Industry subgroup leads provided summaries of their subgroup’s accomplishments from this week.

## **America First Proposals**

FDA provided preliminary responses to Industry's questions about FDA's America First fee incentives proposal. Industry asked if FDA would consider regulatory proposals, including those that are already being discussed in the pre-market subgroup that Industry believes would help improve the regulatory environment and drive greater Phase 1 clinical trials in the US. FDA responded that such proposals would be considered new and out of scope. Industry asked if FDA could confirm the intent is to apply this differential fee to applications including Phase 1 trials that are initiated on or after October 1, 2027 (i.e. the effective date of PDUFA VIII). FDA stated it was still considering. FDA suggested that changes to the fee structure may be needed to maintain predictable fees and limit fluctuations in the application fee, and Industry expressed concern with adjusting the existing fee structure comprised of 20% application fee and 80% program fees. Industry stated a change in fee structure would be a new proposal. FDA noted that FDA's proposal does not include changes to existing fee waivers, with the exception of the proposed changes to the small business waiver. Industry raised additional questions about how FDA proposes to define eligibility for the reduced fee, and FDA committed to considering definitions.

## **Non-Orphan Indication Supplement Fee Proposal**

FDA provided responses to Industry's questions about 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. FDA noted that this proposal does not include changes to existing waivers, and FDA clarified that an applicant would only pay the new fee for the first non-orphan indication submitted for an application. Industry reiterated concerns that FDA's proposal could reduce incentives for rare disease drug development, and FDA asked clarifying questions about the drivers of industry decisions regarding rare drug development.

## **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 clarified the resource agreement 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 continue discussing FDA's America First proposals at upcoming meetings.