Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

February 24, 2026 | 9:30am – 10:30am

Virtual Format

MEETING PURPOSE

To provide additional responses to Industry questions about FDA's America First fee incentives proposal.

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Annetta Beauregard	BIO
Emily Ewing	CDER	Rob Berlin	BIO (Vertex)
Mary Thanh Hai	CDER	Steve Berman	BIO
Amy Ramanadham	CDER	Adora Ndu	BIO (Bridge Bio)
Larry Lee	CDER	Drew Sansone	BIO (Alkermes)
Josh Barton	CDER	Derek Scholes	BIO
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Kelly Goldberg	PhRMA
Christine Hunt	OCC	Kristy Lupejkis	PhRMA
Kate Greenwood	OCC	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

MEETING SUMMARY

FDA provided additional responses to questions posed by Industry at previous meetings, regarding FDA's America First fee incentives proposal.

America First Fee Incentives Proposal

FDA confirmed that, under FDA's proposal, the fee differential would apply to applications for which the Phase 1 trials were initiated on or after the start of PDUFA VIII (October 1, 2027). FDA confirmed the proposal would not be applied retroactively. FDA acknowledged a question Industry posed about whether trials initiated simultaneously in the United States and other countries would qualify for the reduced fee. FDA shared that although the Agency is still developing definitions and eligibility criteria, FDA anticipates that trials would need to be started in the United States to qualify for the reduced fee. Industry provided additional considerations for FDA's development of definitions, including scenarios related to clinical holds and participant recruitment for rare and low prevalence diseases. Industry also reiterated concerns that FDA's proposal would require changes to the fee structure and agreed to provide a counterproposal that would not require changes to the fee structure.

Next Steps

FDA and Industry agreed to revisit the America First proposals and the non-orphan indication supplement fee proposal at the next meeting.