Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

March 12, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To discuss the America First fee incentives and non-orphan indication supplement fee proposal and share subgroup progress updates.

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	Drew Sansone	BIO (Alkermes)
Larry Lee	CDER	Derek Scholes	BIO
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Carl Garner	PhRMA (Eli Lilly)
Christine Hunt	OCC	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis	PhRMA
		Katrin Rupalla	PhRMA (J&J)
		Lucy Vereshchagina	PhRMA
		Glen Murphy*	CHPA (Kenvue)

**This participant departed after the America First discussion.*

MEETING SUMMARY

FDA responded to Industry's proposed definition for applications with phase 1 clinical trials anchored in the United States. FDA also responded to Industry's proposed approach to FDA's non-orphan indication supplement fee proposal. The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week.

America First Fee Incentives

Industry shared a proposed definition for anchoring phase 1 clinical trials in the United States and qualifying for the fee incentive. FDA shared initial responses to the proposal and highlighted feasibility concerns associated with verifying the eligibility criteria. Industry raised questions about how investigational new drug applications (INDs) that attempted to meet the proposed criteria but were placed on clinical hold would be handled. Industry also inquired about how an applicant would provide documentation to show that they meet the eligibility criteria.

Industry agreed to revise their proposed eligibility criteria in response to the discussion, and FDA agreed to consider how sponsors might verify that they meet the criteria.

Non-Orphan Indication Supplement Fee Proposal

FDA shared that the Agency agrees that the fee assessed for the first supplement seeking to add a non-orphan indication to an application approved for an orphan indication should be half of the application fee. FDA agreed to draft language for this proposal.

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. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Plan for Next Meeting

FDA and Industry agreed to continue discussing eligibility criteria for the America First fee incentive and to revisit the America First small business waiver proposal at a future meeting.