U.S. FOOD & DRUG ADMINISTRATION

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

March 10, 2026 | 9:30am – 10:30am

Virtual Format

MEETING PURPOSE

To discuss the America First fee incentives proposal and the non-orphan indication supplement fee proposal.

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Annetta Beauregard	BIO
Emily Ewing	CDER	Rob Berlin	BIO (Vertex)
Mary Thanh Hai	CDER	Steve Berman	BIO
Josh Barton	CDER	Adora Ndu	BIO (Bridge Bio)
Issam Zineh	CDER	Drew Sansone	BIO (Alkermes)
Sonday Kelly	CBER	Derek Scholes	BIO
Christine Hunt	OCC	Mark Taisey	BIO (Amgen)
Kate Greenwood	OCC	Donna Boyce	PhRMA (Pfizer)
		Carl Garner	PhRMA (Eli Lilly)
		Kelly Goldberg	PhRMA
		Kristy Lupejkis	PhRMA
		Alison Maloney	PhRMA (Bayer)
		Lucy Vereshchagina	PhRMA
		Glen Murphy	CHPA (Kenvue)
		Carolyn Herrmann	CHPA
		Marcia Howard	CHPA
		David Spangler	CHPA
		Erin Oliver	CHPA (Haleon)

MEETING SUMMARY

Industry responded to FDA's perspectives on the America First fee incentives proposal and provided a counterproposal to FDA's proposal related to orphan drug fee exemptions and exceptions.

America First Fee Incentives

FDA and Industry discussed that, contingent on FDA and Industry agreeing to eligibility criteria for applications with phase 1 clinical trials anchored in the United States, FDA and Industry agree with the fee incentives proposal outlined at the previous meeting, in which qualifying applications would pay half of the application fee. Industry agreed to propose criteria for applications with phase 1 clinical trials anchored in the United States.

Non-Orphan Indication Supplement Fee Proposal

Industry noted previously stated concerns about the impacts of FDA's proposal to assess a fee for the first supplement seeking to add a non-orphan indication to an application approved for an orphan indication. Industry proposed that the fee assessed for such a supplement should be half of the application fee. Industry noted that this approach would be consistent with supplement fees assessed prior to PDUFA VI. Industry also confirmed that, like other supplements, subsequent supplements submitted for non-orphan indications should not pay any fee.

FDA agreed to consider Industry's counterproposal and respond at a future meeting.

Plan for Next Meeting

FDA and Industry agreed to discuss FDA's America First proposal to limit the small business waiver to sponsors based in the United States at a future meeting. FDA also agreed to provide a response to Industry's non-orphan indication supplement fee counterproposal.