Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

January 8, 2026 | 3:30pm – 5:00pm

FDA White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

To share the approach to tracking the resource implications of tentative agreements made during negotiations and provide progress updates for the subgroups.

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	Donna Boyce	PhRMA (Pfizer)
Christine Hunt	OCC	Kelly Goldberg	PhRMA
Kate Greenwood	OCC	Kristy Lupejkis*	PhRMA
		Alison Maloney	PhRMA (Bayer)
		Katrin Rupalla	PhRMA (J&J)
		Lucy Vereshchagina*	PhRMA

**These participants attended virtually.*

MEETING SUMMARY

FDA presented an overview of the Finance subgroup's approach to tracking resources tentatively agreed to for PDUFA VIII. The FDA and Industry subgroup leads also provided summaries of their subgroup's accomplishments from this week.

Approach to PDUFA VIII Finances

FDA shared how the Finance subgroup is tracking the resource implications, in terms of payroll for full-time equivalents (FTEs) and other direct costs (ODCs), of tentative agreements reached

during this negotiation. FDA noted that the net resources are calculated by subtracting any costs that FDA and Industry agree to discontinue from new costs agreed to.

FDA and Industry acknowledged the approach shared and the subgroup leads agreed to continue sharing the resource implications of their tentative agreements.

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

Wrap Up

FDA shared that the Agency will send Industry a counterproposal for the Information Technology (IT) section of the PDUFA VIII commitment letter. FDA also acknowledged the need to continue discussions about FDA's America First proposals.