



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

January 6, 2026 | 9:30am – 10:30am

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

MEETING PURPOSE

To establish goals and processes for the remaining months of negotiations.

PARTICIPANTS

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai	CDER
Amy Ramanadham	CDER
Larry Lee	CDER
Josh Barton	CDER
Issam Zineh	CDER
Sunday Kelly	CBER
Christine Hunt	OCC
Kate Greenwood	OCC

INDUSTRY

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

**These participants attended virtually.*

MEETING SUMMARY

FDA welcomed the FDA and Industry negotiating teams back from the holidays and reviewed the timeline for negotiations. FDA and Industry discussed processes for efficient negotiations and established plans for the upcoming negotiating meetings.

Goals and Schedule for the New Year

FDA reviewed the schedule for the rest of negotiations and reiterated that negotiations must be completed by the end of March. FDA and Industry discussed best practices for addressing

challenging topics, including processes for escalating a topic if an agreement cannot be reached within the subgroup.

FDA also reviewed remaining topics for the Steering Committee to negotiate before the end of negotiations. Industry expressed interest in restarting discussions on FDA's America First proposals, to ensure sufficient time to negotiate.

FDA notified Industry that FDA will conduct its third Stakeholder Consultation Meeting with patient and consumer representatives on January 9th. The topics for the meeting include Patient-Focused Drug Development, the Sentinel Initiative, Post-Marketing Safety Requirements and Risk Evaluation and Mitigation Strategies (REMS) Assessments, and FDA's proposal to assess fees for non-orphan indications submitted to orphan-only products. Industry emphasized their interest in understanding stakeholder perspectives on how changes to the orphan drug fee exemption may impact research and development of orphan drugs.

Next Steps

The goal for the next meeting on January 8th will be to clarify how the Finance subgroup is approaching calculations for PDUFA VIII resources, share progress updates from the subgroups, and plan for next meeting. FDA acknowledged that FDA continues to develop a response to Industry's counterproposal for Information Technology (IT), and Industry continues to develop a response to FDA's proposal for Cell and Gene Therapy (CGT) language to be included in the commitment letter.