



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

February 5, 2026 | 3:30pm – 5:00pm

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

MEETING PURPOSE

To share updates from the subgroups.

PARTICIPANTS

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Mary Thanh Hai*	CDER
Amy Ramanadham*	CDER
Larry Lee	CDER
Josh Barton	CDER
Sonday Kelly*	CDER
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
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla*	PhRMA (J&J)
Lucy Vereshchagina	PhRMA

**These participants attended virtually.*

MEETING SUMMARY

The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week.

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.

Next Steps

FDA and Industry agreed to revisit America First proposals next week and to continue working on commitment letter language for Cell and Gene Therapy and Digital Health Technologies (originally part of the Information Technology section of the commitment letter).