



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

December 11, 2025 | 3:30pm – 5:00pm

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
Issam Zineh	CDER
Sonday 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

MEETING SUMMARY

The FDA and Industry leads from each subgroup provided a summary of their subgroup's accomplishments from the week and their plans for the following week. FDA and Industry also discussed strategies for efficient negotiations meetings.

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. The subgroups continued detailed

discussions of specific topics, and some subgroups began drafting language for the commitment letter. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Next Steps

FDA and Industry briefly discussed strategies for efficient negotiations meetings, including potential use of longer caucuses during FDA-Industry meetings.

The goal for the next meeting on December 18th will be to discuss Industry's feedback on FDA's Information Technology and Cell and Gene Therapy proposals, summarize perspectives shared by patient and consumer groups at the second stakeholder consultation meeting (held on December 5th), and share progress updates from the subgroups.