



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

March 26, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To share subgroup progress updates and plan for the remainder of negotiations.

PARTICIPANTS

FDA

Andrew Kish	CDER
Emily Ewing	CDER
Amy Ramanadham	CDER
Larry Lee	CDER
Josh Barton	CDER
Issam Zineh	CDER
Sonday Kelly	CDER
Christine Hunt	OCC
Kate Greenwood	OCC

INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Lucy Vereshchagina	PhRMA

MEETING SUMMARY

The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week. FDA and Industry discussed plans for preparing the commitment letter and continued meetings.

Subgroup Progress Updates

The FDA and Industry subgroup leads from the Pre-Market; Chemistry, Manufacturing, and Controls (CMC); and Finance subgroups, as well as the Steering Committee, summarized their accomplishments and plans for next steps. The subgroups acknowledged that they are reviewing commitment letter language; as such, not all subgroups held formal meetings. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

Plan for Remainder of Negotiations

FDA noted that FDA and Industry are focused on reviewing commitment letter language. To allow time for review, FDA proposed that the Steering Committee and subgroups only reconvene as needed to discuss commitment letter language. FDA also suggested that the Steering Committee will reconvene when both parties have reviewed the full commitment letter draft. Industry agreed with this approach.