Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

March 19, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To discuss the America First small business waiver proposal, discuss commitment letter language, share subgroup progress updates, and plan for the remainder of negotiations.

PARTICIPANTS

FDA		INDUSTRY	
Andrew Kish	CDER	Annetta Beauregard	BIO
Emily Ewing	CDER	Rob Berlin	BIO (Vertex)
Mary Thanh Hai	CDER	Steve Berman	BIO
Larry Lee	CDER	Drew Sansone	BIO (Alkermes)
Josh Barton	CDER	Derek Scholes	BIO
Sonday Kelly	CBER	Mark Taisey	BIO (Amgen)
Christine Hunt	OCC	Donna Boyce	PhRMA (Pfizer)
Kate Greenwood	OCC	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

Industry inquired about FDA's proposed eligibility criteria for small businesses based in the United States. FDA and Industry discussed PDUFA VIII revisions to Section III of the PDUFA VII commitment letter. The FDA and Industry subgroup leads provided summaries of their subgroup's accomplishments from this week. FDA and Industry discussed a timeline for preparing a draft of the PDUFA VIII commitment letter.

America First Small Business Waiver

Industry inquired about how FDA plans to define "based in the United States" for the Agency's proposal to limit the small business waiver to applicants based in the United States. FDA and Industry discussed a possible approach to determining whether an applicant is based in the United States. FDA agreed to send a proposed approach to Industry following the meeting.

Commitment Letter Language

FDA shared draft commitment letter language for Section III of the commitment letter, which relates to hiring and retention of review staff. FDA and Industry discussed how best to streamline the section. Industry agreed to review FDA's draft language.

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

Plan for Remainder of Negotiations

FDA and Industry discussed a timeline for preparing and reviewing a complete draft of the PDUFA VIII commitment letter. FDA and Industry agreed to strive to conclude negotiations meetings in early April.