Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

January 29, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To revisit FDA's America First proposals, discuss FDA's proposed approach to the hiring section of the commitment letter, and 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

**These participants departed after the America First discussion.*

INDUSTRY	
Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Adora Ndu	BIO (Bridge Bio)
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)
Lucy Vereshchagina	PhRMA
Glen Murphy*	CHPA (Kenvue)
Marcia Howard*	CHPA
David Spangler*	CHPA

MEETING SUMMARY

Industry reiterated their perspectives on FDA's America First proposals. FDA proposed an approach to the hiring section of the PDUFA VIII commitment letter. The FDA and Industry subgroup leads also provided summaries of their subgroup's accomplishments from this week.

Revisit America First Proposals

FDA asked Industry clarifying questions about their perspectives on FDA's America First proposals, which include a proposal to limit the small business waiver to applicants based in the United States (U.S.) and a proposal to create fee incentives for domestic drug development. Industry reiterated that they are committed to seeking a solution that helps facilitate drug development, and in particular Phase 1 clinical trials, in the United States. Industry highlighted their concerns with the feasibility of FDA's IND fee-related proposal and stated that they require answers to the feasibility questions they posed during the Steering Committee meeting on January 15th and submitted to FDA. Industry also emphasized their concerns that aspects of the proposals could create unintended consequences that may drive drug development away from the United States and do not focus on the efficiency of early drug development, which is a primary driver of Industry decision-making and where to begin early clinical trials. Industry noted that fees may have a disproportionate impact on small companies, and that, especially in the case of an over-the-counter switch, the company submitting the marketing application may not have had control over where the drug development took place. Industry reiterated that they want to work with FDA to find solutions and asked whether FDA would consider alternative proposals aimed at increasing efficiencies in early drug development. FDA agreed to consider Industry's feedback.

Hiring Goals

FDA asserted that completion of the commitments agreed to in the PDUFA commitment letter is contingent upon FDA meeting hiring goals stated in the commitment letter and collecting PDUFA fees. FDA proposed that due dates for commitments that require additional staffing resources should be timed to allow for FDA to hire and train the necessary staff, and FDA confirmed that this approach matches PDUFA VII and other previous PDUFA authorizations. Industry asked clarifying questions about this approach, and FDA agreed to draft language for the hiring section of the PDUFA VIII commitment letter.

Subgroup Progress Updates

Prior to providing progress updates, FDA responded to the concern that Industry raised on January 22nd that FDA subgroups may not all be negotiating from an assumption that PDUFA will be staffed to its funded capacity. FDA confirmed that FDA plans to staff the PDUFA program to the capacity funded by PDUFA VII, and that new resources requested by FDA in PDUFA VIII negotiations would be needed for FDA to complete additional activities beyond PDUFA VII capacity.

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. FDA and Industry agreed that, as FDA has not responded to the questions posed by Industry, FDA and Industry have reached an

impasse on the element of FDA's America First proposal that would result in FDA assessing fees prior to the submission of a marketing or licensing application. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

After the subgroups provided updates, FDA and Industry discussed the shared goal of increasing efficiency via PDUFA negotiations. Industry shared that they prioritize both the efficiency of FDA operations and the efficiency of drug development. FDA noted that some enhancements proposed by Industry to increase the efficiency of drug development may, in the Agency's view, decrease the efficiency of FDA operations. Industry explained how increased information sharing and transparency by FDA would increase the efficiency of drug development and how this would, in turn, lead to FDA review efficiencies through the submission of data better aligned with FDA expectations as well as potentially reducing the number of meeting requests as the information would be publicly available.

Next Steps

FDA and Industry agreed that they look forward to in-person negotiations next week.