Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

January 15, 2026 | 3:30pm – 5:00pm

Virtual Format

MEETING PURPOSE

To revisit FDA's America First proposals and provide progress updates for 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 discussion of America First proposals.*

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)
Carl Garner	PhRMA (Eli Lilly)
Kelly Goldberg	PhRMA
Kristy Lupejkis	PhRMA
Alison Maloney	PhRMA (Bayer)
Katrin Rupalla	PhRMA (J&J)
Lucy Vereshchagina	PhRMA
Glen Murphy*	CHPA (Kenvue)
Marcia Howard*	CHPA
David Spangler*	CHPA
Erin Oliver*	CHPA (Haleon)

MEETING SUMMARY

FDA presented a recap of the Agency's America First proposals and the discussion of these proposals so far in PDUFA VIII negotiations. Industry shared questions about how FDA proposes to operationalize these proposals. The FDA and Industry subgroup leads also provided summaries of their subgroup's accomplishments from this week.

Revisit America First Proposals

FDA provided a recap of the Agency'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. FDA shared that so far, FDA has presented the proposals and responded to clarifying questions from Industry, Industry has shared perspectives on the fee incentives proposal, and Industry has confirmed that FDA and Industry should discuss these proposals at the Steering Committee (as opposed to the Finance subgroup).

FDA responded to clarifying questions from Industry about the small business waiver proposal. Industry expressed concern about the complexity of determining whether a company is based in the U.S., and FDA agreed to further discussions about the definition of "U.S-based applicants".

FDA reiterated that the fee proposal is intended to encourage sponsors to conduct Phase I studies in the U.S. via an incentive. FDA highlighted that this proposal is not intended to be a tax on investigational new drug applications (INDs) or early phase drug development.

FDA also reviewed the feedback previously shared by Industry in response to the fee incentives proposal, namely, that although industry shares the goal of increasing early clinical research in the United States, PDUFA may not be the best vehicle for desired outcome, incentives are more effective than penalties, and FDA and Industry need to consider unintended consequences. Industry agreed with FDA's summary and re-emphasized that Industry shares the goals of furthering U.S. competitiveness and incentivizing Phase 1 clinical trials in the U.S. Industry also reiterated their concerns that (1) FDA's proposal interferes with a fee structure that was designed to limit risks in an already uncertain drug development process, (2) FDA's proposal may not affect the primary drivers of drug development occurring outside the U.S. and there should be a broader policy discussion on addressing regulatory and health system barriers to U.S. clinical trials, and (3) FDA's proposal may have unintended consequences, which could include driving more companies to develop drugs outside the U.S. and that in general, incentives are more effective than penalties, especially in early IND phase. Industry also asked FDA whether it had considered language from a 2018 Senate Report expressing concern that "user fee negotiations between FDA and regulated industries have resulted in goals letters submitted to Congress containing policy changes that require statutory changes, and presume that Congress will adopt suggested statutory changes."

Following the recap, Industry provided an extensive list of questions about how the FDA would apply and administer these fees. FDA acknowledged that Industry's questions highlight concerns with a potential fee being administered in the IND phase. FDA agreed to consider Industry's questions and revisit the proposal at a later meeting.

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

The goals for the next meeting on January 22nd will be to provide a summary of feedback shared at the Stakeholder Consultation Meeting held on January 9th and share progress updates from the subgroups.