Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Steering Committee

November 18, 2025 | 9:30am – 10:30am

Virtual Format

MEETING PURPOSE

To agree on progress goals for the end of the 2025 calendar year and review FDA's America First proposal to limit the small business waiver to applicants based in the United States of America (U.S.).

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	Adora Ndu	BIO (Bridge Bio)
Josh Barton	CDER	Drew Sansone	BIO (Alkermes)
Issam Zineh	CDER	Mark Taisey	BIO (Amgen)
Sonday Kelly	CBER	Donna Boyce	PhRMA (Pfizer)
Christine Hunt	OCC	Carl Garner	PhRMA (Eli Lilly)
Kate Greenwood	OCC	Kelly Goldberg	PhRMA
		Kristy Lupejkis	PhRMA
		Alison Maloney	PhRMA (Bayer)
		Katrin Rupalla	PhRMA (J&J)
		Lucy Vereshchagina	PhRMA

MEETING SUMMARY

FDA and Industry agreed on goals for each subgroup to work toward by the end of the calendar year, discussed FDA's proposal related to the small business waiver, and established a plan for the next Steering Committee meeting.

Goals for the End of the Calendar Year

To help ensure timely and efficient negotiations, FDA proposed progress goals for each subgroup to accomplish by the end of the 2025 calendar year. FDA's proposed goals reflect the number and

complexity of proposals assigned to each subgroup. FDA proposed that the Post-Market Safety and Chemistry, Manufacturing, and Controls (CMC) subgroups should strive for tentative agreement on all proposals by the end of the calendar year. FDA also proposed that the Steering Committee strive to reach tentative agreement on all proposals, except the proposal to introduce fee incentives for domestic drug development, by the end of the calendar year. FDA proposed that the Pre-Market and Finance subgroups review all proposals in detail by the end of the calendar year and that the Pre-Market subgroup also aim to agree on which, if any, proposals to discontinue by the end of the calendar year.

Industry expressed that FDA's proposed goals are ambitious but agreed to work toward these goals.

FDA Proposal: Limit Small Business Waiver to U.S.-Based Applicants

FDA presented the Agency's America First proposal to adjust the eligibility criteria for the small business waiver such that only applicants based in the United States are eligible to receive the waiver. FDA stated that currently, to qualify for the waiver, an applicant must demonstrate that it has less than 500 employees, including affiliates, has not previously submitted a marketing application to FDA, and does not have an FDA-approved product. FDA also clarified that the small business waiver only applies to the application fee, not the program fee. FDA shared that it understood the intent of the small business waiver to be to help a small business get their first product to market, and FDA added that three-quarters of the small business waivers awarded since 2022 were awarded to U.S.-based applicants.

Industry inquired about how FDA proposes to define "U.S.-based applicants," and FDA noted that FDA and Industry will need to discuss definitions in future meetings. Industry also raised concerns about how the proposed change might impact submissions seeking to address unmet medical needs. FDA noted its position that there are other waivers relevant to unmet medical needs that FDA is not proposing to change and that FDA has not reviewed the small business waivers awarded in the past to assess whether an application for an unmet medical need would have been affected. Industry agreed to consider whether they would prefer to continue discussing this proposal at the Steering Committee or in the Finance Subgroup.

Next Steps

FDA reviewed the proposed schedule for the remaining Steering Committee meetings in November and December. Industry inquired about FDA's approach to revising the Information Technology and Cell and Gene Therapy sections of the PDUFA VII commitment letter, and FDA clarified that the Agency is focused on removing commitments that are no longer relevant and does not plan to introduce new commitments. FDA and Industry acknowledged that the rapid rate of change in information technology would be difficult to plan for in the PDUFA VIII commitment letter.

The goals for the next meeting on November 20th will be to review feedback from the first public stakeholder consultation meeting and share progress updates from the subgroups.