



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Steering Committee

November 20, 2025 | 3:30pm – 5:00pm

Virtual Format

### MEETING PURPOSE

To report on the first stakeholder consultation meeting 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
Sonday Kelly	CDER
Christine Hunt	OCC
Kate Greenwood	OCC

#### INDUSTRY

Annetta Beauregard	BIO
Rob Berlin	BIO (Vertex)
Steve Berman	BIO
Adora Ndu	BIO (Bridge Bio)
Drew Sansone	BIO (Alkermes)
Mark Taisey	BIO (Amgen)
Donna Boyce	PhRMA (Pfizer)
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

FDA summarized for Industry the first stakeholder consultation meeting, held on November 7<sup>th</sup>. Following the summary, the FDA and Industry subgroup leads provided a summary of their subgroup's accomplishments from this week and their plans for upcoming weeks.

#### Stakeholder Meeting Summary

FDA began its summary by noting that for every month that FDA conducts negotiations meetings with Industry, FDA also holds a stakeholder consultation meeting with patient and consumer groups that registered to participate. FDA shared that the first stakeholder consultation meeting, held on November 7, focused on explaining the reauthorization process, clarifying the scope of

PDUFA negotiations, and collecting initial perspectives from the participants. FDA highlighted that stakeholder participants expressed concern about the lack of transparency around FDA-Industry negotiations and that stakeholders want to provide feedback that is relevant to the negotiations. FDA also reported that priority topics expressed by the stakeholder participants include pilots and programs related to the use of regulatory decision tools (e.g., Patient-Focused Drug Development Program, Advancing Real-World Evidence Pilot Program), post-market safety (e.g., resources for post-market safety, balance of safety and effectiveness standards against the speed of drug development), and transparency around FDA's decision-making processes (e.g., recent decline in Advisory Committee meetings). Industry acknowledged the importance of stakeholder feedback and desire to hear more about stakeholders' priorities. There were no questions about the summary shared by FDA.

### **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. The subgroups continued detailed discussions of specific topics, in accordance with their previously established schedules. The Pre-Market subgroup achieved tentative agreement on one proposal topic. For additional details about the subgroup meetings, please see the meeting minutes for those subgroups.

### **Next Steps**

FDA and Industry agreed to continue discussions of FDA's America First proposal to limit the small business waiver to U.S.-based companies at the Steering Committee, as opposed to in the Finance subgroup. Industry noted that they would prefer to discuss all America First proposals at the Steering Committee.

The tentative goal for the next meeting on December 2<sup>nd</sup> will be to revisit FDA's America First proposal to introduce fee incentives for domestic drug development. Time permitting, the Steering Committee will also discuss FDA's proposed edits to the Information Technology section of the commitment letter.