



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

January 7, 2026 | 1:00 pm-2:30 pm

FDA White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

The purpose of this meeting was to continue PDUFA VIII negotiations between the FDA and Industry Post-market Safety Subgroups, focusing on refining the draft commitment language and continued discussion of the Sentinel proposal.

PARTICIPANTS

FDA

Amy Ramanadham	CDER
Jason Bunting	CDER
Bob Ball	CDER
Neha Gada	CDER
Craig Zinderman	CBER

Industry

Katrin Rupalla	PhRMA (Johnson & Johnson)
Mark Taisey	BIO (Amgen)
Lucy Vereshchagina	PhRMA
Derek Scholes	BIO
Ryan Kaat	PhRMA
Annetta Beauregard	BIO

MEETING SUMMARY

The January 7, 2026, PDUFA VIII negotiations meeting focused on FDA's response to Industry's counterproposal and draft commitment letter language. Both parties shared their respective perspectives on various aspects of the Sentinel proposal.

Topic 1: Draft Commitment Language

The FDA Post-market Safety Subgroup presented a simplified approach to the language for the PDUFA VIII commitment letter. FDA and Industry agreed to continue discussions on specific draft commitment language, including on how these commitments will relate to ARIA sufficiency determinations and on establishing a cadence of meetings between FDA and Industry on Sentinel. In response to an Industry-raised pain point, participants discussed whether an existing practice used in the Center for Biologic Evaluation and Research (CBER) process for reviewing concept briefs for non-interventional safety studies prior to drug approval could be expanded to the Center for Drug Evaluation and Research (CDER). FDA and Industry discussed whether such an effort would be feasible as a formal commitment or whether it would need to be pursued as a pilot outside the PDUFA negotiations. FDA indicated that as a commitment, it would likely also fall

under the purview of the pre-market subgroup. FDA and Industry agreed to explore further ways to address a proposal around concept briefs.

Next Steps

- FDA will revise the draft commitment language using a simplified approach and will incorporate changes discussed during the meeting.
- FDA and Industry will take the concept brief proposal back for internal discussion.