



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

January 21, 2026 | 1:00 pm-2:00 pm

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 possible PDUFA VIII commitment letter language related to Sentinel, including exploring the potential for Industry voluntary submission of concept briefs for evaluating serious safety issues during the postmarketing period.

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 21, 2026, PDUFA VIII negotiations meeting continued discussions on possible PDUFA VIII commitment letter language. The meeting focused on aligning on PDUFA VIII commitment language and exploring approaches to improve planning for non-interventional postmarketing requirement (PMR) studies.

Topic 1: PDUFA VIII Commitment Letter Language

FDA and Industry agreed to revise the draft PDUFA VIII commitment language and to retain the pertinent Risk Evaluation and Mitigation Strategies (REMS) language from the PDUFA VII commitment letter. FDA and Industry also continued discussions regarding the potential value of FDA receiving voluntary concept briefs for non-interventional studies to be conducted during the postmarketing phase of the product lifecycle, and how such an approach might be reflected in the PDUFA VIII commitment letter. FDA and Industry acknowledged the potential value of concept brief submissions and acknowledged mutual interest in its potential benefits, such as improving

non-interventional PMR protocol submissions and allowing earlier identification of proposals that may not be accepted by the FDA.

Next Steps

- FDA will revise the draft commitment language and circulate it to Industry for review in advance of the next subgroup meeting.