



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

January 28, 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 finalizing counterproposal language regarding concept briefs, discussing resource requirements, and resolving outstanding issues in the draft PDUFA VIII Commitment Letter.

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 28, 2026, PDUFA VIII negotiations meeting between FDA and Industry Post-market Safety Subgroup resulted in alignment on PDUFA VIII Commitment Letter language for concept briefs and agreement in principle on resource allocations.

Next Steps

- FDA and Industry to finalize PDUFA VIII Commitment letter language via email. No further negotiation meetings will be necessary.