



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

December 17, 2025 | 1:00 PM to 2:30 PM

Virtual Format

MEETING PURPOSE

The purpose of this meeting was to continue PDUFA VIII negotiations between FDA and Industry, focusing on resource allocation and FDA’s preliminary responses to Industry’s counterproposal, and to determine if FDA and Industry envision an aligned path forward regarding PDUFA VIII commitment language.

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)
Derek Scholes	BIO
Ryan Kaat	PhRMA
Annetta Beauregard	BIO

MEETING SUMMARY

The December 17, 2025, PDUFA VIII negotiations meeting focused on FDA sharing additional information on the resource allocations for Sentinel from PDUFA VI and PDUFA VII and FDA’s preliminary response to Industry’s counterproposal. FDA and Industry agreed to continue negotiations acknowledging that there is not yet alignment on the final PDUFA VIII commitment language or resourcing for Sentinel 3.0.

Topic 1: Resource Allocations for Sentinel from PDUFA VI and VII

FDA shared information of the full-time equivalents (FTEs) by position (e.g., epidemiologist, medical officer, pharmacist) across the Center for Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER). Industry inquired where additional FTEs requested by FDA would be allocated if agreed upon under PDUFA VIII negotiations. FDA conveyed these FTEs would focus on analytical capability and safety analyses, with specific allocations to be determined. FDA shared the publicly available information on the funding ceiling of the Sentinel Contract noting that Sentinel funding can be variable based on unforeseen

need, and the ceiling costs may be increased such as they were during the COVID-19 pandemic and with the current contract extension year.

Topic 2: FDA preliminary response to Industry counterproposal

FDA opened the discussion noting that, given Industry and FDA are aligned on a back-to-basics approach regarding Sentinel, FDA envisions maintaining a similar approach to the commitments. FDA proposed further negotiations on some aspects of Industry's counterproposal; however, FDA noted certain aspects of Industry's counterproposal are not feasible. Industry noted they appreciate the FDA feedback, clarified their interest to dialogue about ARIA sufficiency determinations, and welcomed the opportunity to continue discussions before verbiage for the commitment letter is finalized.

FDA and Industry agreed to continue negotiations, acknowledging that they are not yet ready to finalize the PDUFA VIII commitments as more dialogue is needed.

Next Steps

1. FDA and Industry will continue negotiations on potential PDUFA VIII commitment letter language.