Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

December 10, 2025 | 1:00 pm–2:30 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 commitments and associated resources to recommend as part of PDUFA VIII reauthorization, to sustain Sentinel capabilities and continue existing PDUFA user fee support for Sentinel. The meeting included FDA presentations on Active Risk Identification and Analysis (ARIA) System sufficiency determinations and Industry's counterproposal for PDUFA VIII commitments.

PARTICIPANTS

FDA		Industry	
Amy Ramanadham	CDER	Katrin Rupalla	PhRMA (Johnson & Johnson)
Jason Bunting	CDER	Mark Taisey	BIO (Amgen)
Bob Ball	CDER	Lucy Vereshchagina	PhRMA
Neha Gada	CDER	Derek Scholes	BIO
Craig Zinderman	CBER	Ryan Kaat	PhRMA
		Annetta Beauregard	BIO

MEETING SUMMARY

The December 10, 2025, PDUFA VIII negotiations meeting focused on FDA's presentation of ARIA insufficiency root causes and Industry's counterproposal for enhanced commitments around transparency, reporting, and sponsor access to Sentinel data. Both parties agreed to continue negotiations with FDA developing a response to Industry's counterproposal while providing additional transparency on resource allocation and full-time equivalents (FTE) distribution for Sentinel allocated during PDUFA VI and PDUFA VII.

Topic 1: ARIA Sufficiency Determinations

FDA shared that FDA tracks and analyzes reasons for insufficiency to understand gaps in the ARIA system and inform program development activities. Root cause analysis revealed that most of the root causes for ARIA insufficiency are due to claims data limitations and methodological

gaps. The Sentinel Real World Evidence Data Enterprise (RWE-DE) has demonstrated that many of these issues are solvable through improved data linkages and advanced analytical tools. FDA emphasized that lessons learned from these analyses and development of the RWE-DE will be valuable for the operations of Sentinel 3.0, even if the same system architecture is not maintained. The Sentinel Innovation Center's extensive efforts to develop data infrastructure, establish data linkages, advance analytics capabilities, and address methodological gaps will provide valuable insights and improvements that will be incorporated into future systems.

FDA noted that pregnancy-related ARIA insufficiency has been evaluated as part of the ongoing pregnancy demonstration projects discussed in previous meetings. During this discussion, it was highlighted that pregnancy safety linkage data is robust, with Sentinel capacity for 6 million mother-infant pairs.

Topic 2: Industry Counterproposal to FDA's Proposed PDUFA VIII Commitments

Industry acknowledged the value of Sentinel for monitoring product safety and presented a counterproposal outlining key areas of interest, including greater transparency around ARIA sufficiency determinations, expanded sponsor access to Sentinel data and analysis, and quarterly meetings between the FDA and Industry to provide updates on Sentinel.

FDA asked several clarifying questions to better understand the counterproposal to inform subsequent internal discussions.

Topic 3: Resource Questions and Transparency

Industry requested additional financial information, including Sentinel resources under PDUFA VI and PDUFA VII. FDA previously shared full-time equivalent (FTE) distributions across the Centers, agreed to consider providing job-title detail, and declined to provide project-level information.

Industry also asked for information about total annual expenditures, broken out by funding source (i.e., budget authority vs. user fees), for fiscal years 2018-2025. FDA explained that these figures reflect historical costs. To obtain a more accurate estimate of future expenses, FDA encouraged Industry to review the forthcoming Sentinel 3.0 Request For Proposal (RFP) once publicly posted, as it will provide information on the contracts ceiling costs. Industry indicated its support for Sentinel over the last two PDUFA authorizations but reiterated the need for more granular detail on Sentinel funding sources. Industry noted its position that PDUFA funding was intended to supplement not replace budget authority.

Next Steps

- Industry will share their counterproposal in writing, and FDA will consider what may be feasible through internal discussions.

- FDA will explore what additional resource and cost information can be shared with Industry.
- FDA and Industry will continue negotiations on potential PDUFA VIII commitment letter language.