Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Post-market Safety Subgroup

November 5, 2025 | 1:00 PM to 2:00 PM

Hybrid Meeting: FDA White Oak Campus, Silver Spring, MD and Virtual Format

MEETING PURPOSE

This was the first meeting between FDA and Industry Post-market Safety Subgroups for PDUFA VIII negotiations. The purpose of this meeting was to introduce the negotiating teams, review ground rules and meeting logistics and to begin discussion of FDA's proposal for the sustainability of current Sentinel capabilities.

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

This meeting was the first meeting between FDA and Industry Post-market Safety Subgroup for PDUFA VIII negotiations. The meeting began with introductions from FDA and Industry participants and review of established ground rules. FDA presented, at a high level, their interest in sustaining the Sentinel system and highlighted the agency's perspective on the system's significant public health value through extensive and impactful work. FDA emphasized the Agency's focus on maintenance of current capabilities rather than pursuing expansion. FDA's proposal called for continued industry support for Sentinel. Industry raised questions about current challenges with and planned enhancements for the Sentinel system. They also asked

about the status of PDUFA VII commitments and deliverables related to Sentinel. Both parties agreed on a structured approach for future meetings with specific action items.

Topic 1: Opening Remarks and Sentinel PDUFA VIII Proposal

FDA delivered opening remarks that emphasized the Agency's century-long commitment to safety and the shared responsibility between FDA and industry for post-market safety. FDA's Post-market Safety Subgroup Lead highlighted that pharmacovigilance data supports regulatory decisions, and that FDA has progressed Sentinel initiatives monitoring millions of health records. The FDA proposal focuses on sustaining Sentinel capabilities and continuing existing PDUFA user fee support for Sentinel without requesting additional funds for expansion or enhancement of the system. FDA referenced "PDUFA VII Commitment: An Assessment of the Sentinel System (2022 to 2024)," made publicly available on September 30, 2025.

Topic 2: Sentinel 3.0 System Evolution and Architecture

Industry inquired about current challenges and planned enhancements for the Sentinel system. FDA explained that Sentinel 3.0 would transition from the current distributed system to a consolidated platform where data resides centrally and can be accessed across the Agency. FDA referenced its most recent Request for Information (RFI) posted in May 2025, and the Sentinel pre-solicitation notice/synopsis with details about the proposed future operating model changes. As explained in the RFI and reiterated by FDA, the goal of the Sentinel 3.0 System contract is to continue meeting or exceeding the legislative requirements, promote program efficiency, support the anticipated needs of each of the distinctive underlying Sentinel 3.0 components (e.g., Active Postmarket Risk Identification and Analysis (ARIA) system), and ensure sufficient flexibility to address emerging safety issues and rapidly changing public health needs (e.g., public health emergencies).

Topic 3: Real-World Evidence (RWE) and PDUFA VII Commitments

Industry asked about the relationship between Sentinel and RWE, and the status of PDUFA VII commitments. FDA clarified that Sentinel (safety focus under FDA Amendments Act (FDAAA) authority) and Real-World Evidence Program (focused on effectiveness) operate as separate programs under different frameworks, though lessons learned from Sentinel may inform the use of RWE. Regarding PDUFA VII commitments related to Sentinel, FDA provided high-level updates regarding negative controls projects (two projects are ongoing, one each for CDER and CBER) that are underway, with completion due by the end of fiscal year 2027. Additionally, FDA noted that all five demonstration projects for pregnancy safety are underway and remain on the project timeline. Based on the results of the demonstration projects, the Agency committed in PDUFA VII to update the proposed framework and develop a guidance or Manual of Policies and Procedures (MaPP)/ Standard Operating Policy and Procedure (SOPP), as appropriate, to implement a

standardized process for determining necessity and type of pregnancy postmarketing studies including Postmarketing Requirements (PMRs) by the end of PDUFA VII. FDA agreed to provide more details on these PDUFA VII commitments in subsequent PDUFA VIII Post-market Safety Subgroup meetings.

Topic 4: Clarifying Future and Past Resource Allocation

Industry asked whether FDA would seek continued funding for the Sentinel demonstration projects (i.e., negative controls and pregnancy safety) under PDUFA VIII, or whether these projects would be considered akin to a pilot program. FDA confirmed that it would not seek additional funding for these demonstration projects. FDA reiterated it was seeking continued funding for maintenance of Sentinel and not enhancements.

Industry inquired about staffing allocations specific to Sentinel under PDUFA VI and PDUFA VII and how this relates to PDUFA VIII planning. FDA suggested this as a topic for future discussion.

Agenda Topics for Upcoming FDA and Industry Post-market Safety Subgroup Discussions

FDA and Industry discussed agenda topics for future meetings including a presentation on the value and benefits of the Sentinel System, status updates on the PDUFA VII Sentinel pilot projects (pregnancy safety and negative controls), review of FDA resources allocated under PDUFA VI and PUDFA VII and potential future requests from FDA to industry in support of Sentinel, and FDA plans for Sentinel 3.0.