



Prescription Drug User Fee Act (PDUFA) Reauthorization FDA and Industry Postmarket Subgroup, Meeting #6 Summary

November 4, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting is to discuss Sentinel proposals from Industry and FDA as well as FDA’s responses to Industry REMS proposals.

PARTICIPANTS

FDA

Bob Ball	CDER
Jason Bunting	CDER
Nancy Derr*	CDER
Mary Ross Southworth	CDER
Terry Toigo	CDER
Craig Zinderman	CDER

Industry

Robert Kowalski	PhRMA (Novartis)
Ann Kurowski	BIO (Alkermes)
Camelia Thompson	BIO
Lucy Vereshchagina	PhRMA

*Note taker

DISCUSSION SUMMARY

FDA briefly recapped the Postmarket Subgroup’s progress to date. The agency also described some recent accomplishments and actions the Agency is already undertaking, to provide context for the subgroup’s discussions.

Following this brief summary, Industry summarized its current thinking on FDA’s Sentinel proposals and resource needs. The discussion focused on how Sentinel might be useful for the analysis of real-world evidence (RWE) regarding effectiveness in addition to safety analyses. There was brief discussion regarding how the RWE proposal being discussed in the premarket subgroup was related to, but different from, the Sentinel proposal being discussed in the postmarket subgroup. Health outcomes of interest (HOIs) that could be of interest to both Industry and FDA were discussed. FDA is particularly interested in HOIs related to safety, including pregnancy outcomes (the focus of Sentinel to date has been on safety).

The Subgroup discussed various options for Sentinel commitments under PDUFA VII, including resources that would be needed to support various types of commitments.

REMS assessments were addressed briefly but will be discussed again in more detail at the next meeting.

Agenda for Next Meeting

At the next meeting, FDA will provide more information on the resources needed to support Sentinel going forward, including to support possible proposed commitments. Industry will develop draft commitment language for Sentinel for FDA consideration at the next meeting.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.