# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Postmarket Subgroup| Meeting # 5 Summary

*October 28, 2020, 2 – 4pm*
*Virtual Format (Zoom)*

### PURPOSE

The purpose of meeting # 5 of the PDUFA VII Postmarket Subgroup was to continue discussions of possible options of common interest between FDA and Industry around Sentinel and REMS.

### PARTICIPANTS

| FDA | Industry |
|---|---|
| Bob Ball (CDER) | Robert Kowalski (PhRMA, Novartis) |
| Jason Bunting (CDER) | Ann Kurowski (BIO, Alkermes) |
| Nancy Derr* (CDER) | Camelia Thompson (BIO) |
| Mary Ross Southworth (CDER) | Lucy Vereshchagina (PhRMA) |
| Terry Toigo (CDER) | |
| Craig Zinderman (CBER) | |

*Note taker

### DISCUSSION SUMMARY

Both FDA and Industry representatives found this meeting to be helpful in moving discussions to specific topics of mutual interest.

The decision was made to move the ARIA insufficiency proposal to the Premarket Subgroup for negotiation. Industry would like ARIA insufficiency discussions to happen earlier in the review cycle.

Industry presented a number of initiatives that aim to enhance Sentinel's analytic capabilities. After discussion, all agreed to consult with the subject-matter experts on their sides to get input on technical issues and help focus further discussion. Both sides agreed on Sentinel's value now and its potential for future contributions to product safety. Industry expressed interest in expanding Sentinel's capacity in effectiveness analysis. Some discussion was devoted to REMS. However, the REMS discussions will continue at the next meeting.

Industry plans to provide FDA some clarity on one of its more specific Sentinel proposals at a future meeting. FDA plans to share resource requirements related to the Sentinel pregnancy safety and health outcomes of interest (HOI) proposals. FDA will also gather more information on common areas of interest related to REMS.

**Agenda for Next Meeting**

At the November 4th meeting, more time will be spent discussing REMS, especially REMS assessments. FDA also intends to make a more detailed presentation on the value to FDA and Industry on new initiatives in the area of pregnancy safety.

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