



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Postmarket Subgroup| Meeting #1 Summary

September 30, 2020 | 2 – 4pm

Virtual Format (Zoom)

### PURPOSE

To introduce the Postmarket Subgroup members; outline ground rules, virtual environment, and schedule going forward; and launch subgroup discussions on REMS assessments and Sentinel.

### PARTICIPANTS

#### FDA

- Bob Ball (CDER)
- Jason Bunting (CDER)
- Nancy Derr (CDER)\*
- Mary Ross Southworth
- Terry Toigo (CDER)
- Craig Zinderman (CBER)

\*note taker

#### Industry

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

### DISCUSSION SUMMARY

Following introductions, FDA reviewed the ground rules for the virtual meeting and completion of the minutes. The group reviewed the dates for future meetings along with suggested topics for discussion over the course of the negotiations.

FDA proceeded with summaries of FDA's thinking regarding the REMS assessment modernization effort and the Sentinel Initiative. FDA provided additional background information for both areas on accomplishments and on FDA's proposals for PDUFA VII. FDA's REMS proposals focus generally on improving design planning, clarifying expectations, improving review efficiencies, and improving transparency. For Sentinel, FDA emphasized that many opportunities exist for building on the progress of PDUFA VI.

Discussion followed on the FDA presentations and on Industry's more specific questions on FDA's REMS assessment goals and on plans for the Sentinel Initiative.

Industry representatives shared their thoughts on the discussion and proposed deliverables related to PDUFA VII for the Sentinel Initiative. FDA intends to review the questions Industry

raised on REMS and Sentinel with the goals of sharing the agency's specific thoughts and raising any additional questions during the October meetings.

### **Agenda for Next Meeting**

- Everyone will confirm the meetings schedule for November.
- The October 7 meeting will focus on Sentinel, with FDA providing additional detail on the insufficiencies related to ARIA and accomplishments for PDUFA VI; Industry will provide more details on its goals for Sentinel.

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