

Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup| Meeting #2 Summary

October 7, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The main focus of meeting # 2 of the Postmarket Subgroup was to enable FDA to provide a more detailed presentation on the Sentinel Initiative, its history, and its activities since PDUFA VI and to enable industry to discuss its proposals for the Sentinel system.

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 confirmation of the November meeting schedule change, FDA provided an in-depth review of the history of the Sentinel Initiative and its achievements based on its PDUFA VI commitments and resources. FDA described the status of its Active Risk Identification and Analysis (ARIA) System, which FDA uses to track the safety of medical products. Examples of notable achievements include establishment of new research centers and the addition of the Biologics Effectiveness and Safety (BEST) System (launched in October 2017) to expand CBER’s access to new and better data sources, methods, and tools for conducting surveillance and epidemiologic studies for vaccines, blood and blood products, tissues and advanced therapeutics. Brief mention was made of projects under way related to COVID.

Other achievements discussed include the January 2019 publication of the Sentinel Initiative Five Year Strategy (2019 to 2023); the expansion of information available to the public on the Sentinel website; the issuance in August 2020 of a MAPP (Notifying Applicants of Sentinel Analyses and Results); and the growing list of diverse collaborators available to support Sentinel projects. In the interest of transparency, FDA has held numerous public meetings since PDUFA

VI—the next meeting scheduled to take place on October 14, 2020. FDA confirmed that it had met all of its Sentinel-related PDUFA VI commitments on time. FDA underscored the hope of making Sentinel a national resource.

Following the presentation on the Sentinel Initiative, FDA and Industry discussed the ARIA insufficiency memos in more detail.

Agenda for Next Meeting

- The topic for the October 14 meeting is REMS. FDA plans to speak in more detail about REMS assessments.

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