Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup| Meeting # 4 Summary

October 21, 2020, 2 – 4pm
Virtual Format (Zoom)

PURPOSE

The goal for meeting #4 is to review the Sentinel Biologics Effectiveness and Safety (BEST) Initiative (launched in October 2017) and follow up on Industry thoughts around Sentinel and REMS assessment proposals.

PARTICIPANTS

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

*Note taker

DISCUSSION SUMMARY

FDA provided an in-depth presentation on the status of the BEST Initiative following its implementation in 2017. Examples were provided of how BEST is using EHR and claims data to identify possible safety issues, for example, related to the effects/non-effects of vaccine use during pregnancy, or to identify possible allergic reactions to certain biological products. Some examples of possible real-time surveillance projects planned related to Covid-19 vaccines also were presented.

Following a brief discussion around the BEST presentation, Industry and FDA discussed FDA's possible Sentinel proposals and REMS assessment projects. Industry provided examples of potential areas that would benefit from additional FDA guidance and MAPPs related to REMS. FDA and Industry will continue to consider options for REMS and Sentinel.

Agenda for Next Meeting

FDA will meet in the next couple of days to finalize topics for next week's agenda.

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