Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup| Meeting # 3 Summary

October 14, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The main focus of meeting # 3 of the Postmarket Subgroup was to discuss FDA's proposal to improve its REMS assessment program.

PARTICIPANTS

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

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DISCUSSION SUMMARY

Following a presentation on the history of FDA's REMS program, FDA presented its thinking on REMS assessment program enhancements. Discussions included analysis of similarities and differences between the CDER and CBER programs and the benefits of collaboration between the two centers. The agency also laid out the resources it believes it will need to implement improvements to the REMS assessment program.

Most important, FDA's proposed REMS assessment program improvements are intended to ensure that REMS assessments include sufficient information to determine if REMS goals are being met or if modifications are needed.

FDA explained that it had begun a substantial effort to improve and modernize REMS assessments. For example, in 2019, the agency published two guidances: *The Survey Methodologies to Assess REMS Goals that Relate to Knowledge* (about general principles and recommendations related to conducting REMS assessment knowledge surveys) and *The REMS Assessment: Planning and Reporting.* FDA received and is reviewing approximately 250 comments on the two guidances and believes that the comments will be helpful as FDA implements the assessment improvements.

FDA and Industry representatives discussed specific issues and questions of interest related to the REMS assessment program, FDA presented its proposal for the resources that would be needed to enable CDER and CBER to move more quickly to implement program improvements. FDA proposed the establishment of specific performance goals, similar to the review goals it has established for other submissions. Industry will provide feedback on the specific FDA proposals discussed.

Agenda for Next Meeting

The topic for the October 21st meeting is to revisit the Sentinel Biologics Effectiveness and Safety (BEST) System (launched in October 2017) and summarized briefly at the October 7th meeting.

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