Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #9 Summary

December 9, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting was to proceed to a more detailed discussion of FDA's REMS assessment proposal and the Sentinel proposal, including the possibility of Sentinel demonstration projects using analytics and the pregnancy safety project.

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

The meeting began with brief updates on the status of summaries of previous meetings.

FDA began the discussion by summarizing its thinking about the REMS questions Industry had asked at the Dec. 2 meeting. Following a discussion at that meeting, FDA had agreed to take a number of Industry questions on the entire REMS protocol and assessment process back to FDA's REMS experts. FDA outlined its ideas with Industry, concluding that if FDA is able to spend more time "up front" in the process, the assessment portion of the process would ultimately go more smoothly. Industry agreed to take the REMS assessment discussion, including FDA's revised resource estimates, back to its larger group and report back to FDA at the next meeting.

Focus then turned to Sentinel. At the last meeting, Industry had asked for information on PDUFA VI spending. FDA presented a summary of the Sentinel activities that are supported by PDUFA VI resources and that need continuing maintenance in PDUFA VII. FDA also provided details about the Sentinel accomplishments that are described on the Sentinel website. Industry agreed to review the Sentinel PDUFA VI summary more formally and send any questions back to FDA before the next meeting. FDA agreed to consider draft commitment language for the continuing support provided by the PDFUA VI resources after it received Industry feedback.

FDA also summarized its thinking about the Industry's proposal to develop and evaluate new analytic methods and tools for use with Sentinel. FDA outlined a number of questions it had for Industry, asking the Industry Subgroup to take the questions back to their analytics experts. FDA believes that once it has feedback on these questions, it will be able to more precisely define how Industry's proposal to develop and evaluate new analytic methods and tools in Sentinel might be described as commitments. Industry agreed to take the questions back to its experts and proposed sending FDA feedback in advance of the next meeting.

Discussion moved to pregnancy safety, a Sentinel project FDA is very interested in including in the PDUFA VII post-market commitments. FDA is focused on finding methodologies that can optimize the approach to using different methodologies for detecting and evaluating safety issues in pregnancy. Industry expressed interest specifically in evaluating the use of pregnancy registries and electronic healthcare data sources. During this discussion, FDA explained that it would further clarify the demonstration projects with particular attention to industry comments about pregnancy registries and electronic healthcare data sources. FDA agreed to share the draft proposal language with Industry in preparation for the next meeting. Industry agreed to provide its experts' feedback related to specific pregnancy safety demonstration projects. FDA reaffirmed that it would not be able to use continued PDUFA VI funding to support any of the new proposed pregnancy demonstration projects.

There was agreement that the Postmarket Subgroup is making good progress. Both FDA and Industry have shared their proposals, including resource estimates. Members expressed satisfaction that the discussions were now focusing on specific aspects of the proposals and specific resource needs.

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