Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #11 Summary

January 21, 2021, 8 – 10am

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting was to continue discussion on Industry and FDA proposed commitment language.

PARTICIPANTS

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

DISCUSSION SUMMARY

The meeting began with a summary of where Industry and FDA stand on the PDUFA VII proposals. Prior to the meeting, FDA provided Industry revised commitment language and resource requests for some of the commitments. FDA also provided new commitment language around financial reporting of Industry's contribution to funding Sentinel commitments agreed to in PDUFA VI.

REMS

FDA explained a few changes to the REMS assessments proposal including clarification of assessment protocol review versus assessment report review and proposed changes to the commitment timelines. FDA explained revised resource requests and provided the anticipated hiring cadence for FTE's (full-time equivalents). FDA also described new commitment language related to REMS elimination that Industry requested at the previous meeting.

Industry asked that FDA consider accelerating the timelines for the proposed MaPP (manual of policies and procedures) and including additional commitment language describing the timeline for finalizing draft guidance.

Sentinel Enhancements

FDA reviewed with Industry the analytics and pregnancy safety demonstration project commitment language. FDA is continuing work on the pregnancy safety proposal but should have additional information to Industry soon after this meeting.

Negative controls

FDA explained that the cost of the negative controls project can be reduced by eliminating the tool development portion of the project. Even without a tool, the demonstration project findings may be applicable to data sets outside of the Sentinel System. FDA also explained why two negative control demonstration projects were necessary, one in CDER and one in CBER. There are important population differences between therapeutics and vaccines such as a sick versus healthy population. The CDER project would focus on safety while the CBER project would focus on effectiveness. The CDER project will focus on automation of negative control selection while the CBER project will focus on biases related to health seeking behavior.

IPCW

Industry expressed interest in continuing to negotiate a potential IPCW proposal. FDA and Industry explored ways to reduce the cost of the IPCW project including focusing on specific data sources instead of all data partners used in Sentinel. FDA agreed to think through the IPCW proposal more and provide industry with update resource requirements.

Financial Reporting of Industry's Sentinel Contributions

FDA proposed commitment language to report annually on how fee resources provided to support the Sentinel Initiative under PDUFA VI are being utilized. Industry agreed to review the draft commitment language.

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