



Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #12 Summary

January 27, 2021, 2:30 – 4:00pm

Virtual Format (Zoom)

PURPOSE

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

PARTICIPANTS

FDA

Bob Ball	CDER
Jason Bunting	CDER
Mary Ross Southworth	CDER
Terry Toigo	CDER
Craig Zinderman	CBER

Industry

Robert Kowalski	PhRMA (Novartis)
Ann Kurowski	BIO (Alkermes)
Camelia Thompson	BIO
Lucy Vereshchagina	PhRMA

DISCUSSION SUMMARY

Prior to the meeting, Industry provided FDA comments and edits to the commitment language. The meeting discussion was focused on those Industry comments and edits. FDA agreed to provide revised commitment language and resource request documents to Industry for final review after the meeting.

REMS

Industry asked that FDA consider updating relevant guidances with respect to how FDA will incorporate REMS assessment planning into the design of the REMS. FDA and Industry also discussed dates by which draft and final guidances related to REMS assessments should be completed. FDA agreed to consider and update commitment language regarding these items as appropriate.

Sentinel

Maintenance of Sentinel

Industry proposed commitment language related to facilitating public and sponsor access to Sentinel’s distributed data network. FDA agreed to consider the additional commitment language.

FDA and Industry discussed and agreed on other edits to the commitment language focused on the maintenance of Sentinel, including language to report annually on how Industry's contributions associated with PDUFA VI Sentinel commitments are being used.

Pregnancy safety

FDA and Industry reviewed Industry comments on the commitment language related to pregnancy safety demonstration projects. FDA provided additional explanation on why the specific demonstration projects were chosen and what is hoped to be learned from them. FDA agreed to provide revised, clarifying commitment language on the demonstration projects.

Enhanced Analytics: Negative controls and IPCW

Industry explained that they would like to focus efforts on negative controls. Industry requested (and FDA agreed) to add tool development back into the current commitment language – it had been removed in an earlier effort to reduce costs of the negative control project. Industry stated it was no longer interested in pursuing IPCW commitments.

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