Prescription Drug User Fee Act (PDUFA) Reauthorization

FDA and Industry Postmarket Subgroup, Meeting #7 Summary

November 18, 2020, 2 – 4pm

Virtual Format (Zoom)

PURPOSE

The purpose of this meeting is to review Industry and FDA proposed commitment language and clarify any outstanding issues related to specific wording and resources.

PARTICIPANTS

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

*Note taker

DISCUSSION SUMMARY

The only administrative issue involved confirming the next Subgroup meeting on December 2.

The Subgroup reviewed the draft proposed Industry REMS commitment language. Discussion followed around clarifying the difference between the timing of the assessment plan review and the time needed to review the assessment reports.

The group also discussed Industry and FDA's Sentinel proposals. FDA agreed to provide additional language for some Industry proposals, to enable a better assessment of the needed resources. FDA raised questions around the possible focus of proposed workshops and demonstration projects as well as the types of analysis improvements needed to support Sentinel work on effectiveness. One topic to be discussed more fully at a later meeting relates to identification of health outcomes of mutual interest.

FDA described its proposal on pregnancy safety which included identifying knowledge gaps to aid in framework development, hosting a public meeting, and conducting demonstration projects. FDA agreed to further clarify the resources for the project.

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