FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
January 12, 2016: 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Purpose

To continue discussions on FDA's Sentinel and Safety Communication Proposals.

Participants

FDA		Industry	
Bob Ball	CDER	Beatrice Biebuyck	BIO (Alexion)
Aloka Chakravarty	CDER	Jennifer Boyer	BIO (Alkermes)
Mwango Kashoki	CDER	Jeffrey Francer	PhRMA
Melissa Robb	CDER	Kay Holcombe	BIO
Aaron Sherman	CDER	Paula Rinaldi	PhRMA (Novartis)
Terry Toigo	CDER		
Craig Zinderman	CBER		

Sentinel Proposal:

FDA provided an overview of how resources associated with this proposal would be utilized in the various program offices. FDA explained that resources were needed to support developing and utilizing a more robust Sentinel System. FDA's proposal seeks to develop more capabilities to allow the Sentinel System to be used to answer more types of safety questions and to provide resources needed to develop, interpret, and act on the new safety information. FDA stated this would require sustained resources and would involve developing FDA staff's expertise in this area across program offices. Discussion also addressed possible commitments.

Industry explained the importance of FDA communication to sponsors about use of Sentinel to evaluate safety issues involving a Sponsor's product. FDA stated that they would explore a possible commitment in this area. FDA and Industry discussed the timing of potential commitments over the span of PDUFA VI.

Safety Communications Proposal:

A possible commitment was discussed related to notification of sponsors regarding FDA's quarterly posting of safety issues ("921 postings" as mandated by the Food and Drug Administration Amendments Act of 2007, section 921). There was also discussion of a potential commitment to improve the consistency of FDA's communications with Sponsors upon opening a tracked safety issue.

Agenda for Next Meeting:

FDA and Industry concluded the meeting with an agreement to discuss possible commitment language for Industry's RWE-Efficacy proposal at the next meeting. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.