FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
January 26, 2016: 1:00pm-4:30pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1309

Purpose

To conclude post-market sub-group discussions on Sentinel, Safety Communications, and Real World Evidence.

Participants

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

Summary:

FDA and Industry concluded post-market sub-group discussions and reached tentative agreement on proposed enhancement initiatives in the following three areas:

- Sentinel System
- Safety Communications
- Real-World Evidence (RWE) for use in regulatory decision making

They also addressed outstanding Industry resource questions for the different topic areas. The following is a brief summary of discussion on each proposal.

RWE-Efficacy Proposal:

FDA and Industry discussed the importance of developing a greater understanding of how RWE can be generated and used for regulatory decision making. Towards this end, FDA and Industry discussed the need to further develop FDA staff's expertise in this area. They also agreed on the importance of public stakeholder input to this process.

Sentinel Proposal:

FDA and Industry agreed on the importance of continued expansion and enhancement of the Sentinel System. They also discussed new and ongoing efforts to be transparent about FDA's development and use of the Sentinel System. FDA reiterated that they hoped it could one day become a national resource. FDA and Industry then discussed ways to ensure the long-term resource-stability of the Sentinel System, and its integration into postmarketing safety evaluation practices.

Safety Communications Proposal:

FDA and Industry discussed the importance of a consistent process for managing and overseeing postmarketing safety issues, and notifying Sponsors when a Tracked Safety Issue is opened. Industry

reiterated the importance to Sponsors of having advance notice about FDA safety communications when possible so that the company is prepared to address inquiries from patients, health professionals, and other members of the public. Discussion concluded on this proposal's resource needs.

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