FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
December 2, 2015: 9:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Purpose

To discuss potential commitments related to Industry's Real World Evidence (RWE) proposal, and to prepare for a similar discussion about FDA's Sentinel proposal at a future meeting.

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	Mike Levy	PhRMA
Terry Toigo	CDER	Paula Rinaldi	PhRMA (Novartis)
Craig Zinderman	CBER		

Industry Real World Evidence Proposal:

Industry began by restating that their goal for this proposal is to create clarity and consistency in how RWE could be used to contribute to the benefit/risk assessment. FDA noted that they understood what Industry hoped to achieve, but also noted it was important to clarify that both groups were using the same terminology and understood not only the goals of the proposal, but also the proposed process to achieve those goals. Industry stated that an important aspect of their proposal is obtaining and incorporating the input of expert stakeholders. FDA agreed that stakeholder input is important but questioned other aspects of Industry's proposal. FDA agreed to provide edits to Industry's proposed process language for continued discussion at a future meeting.

Industry also asked if FDA had a resource estimate for the proposal. FDA provided an approximation, and explained that clarity around the proposal would be needed to provide a more exact resource assessment. FDA agreed to provide a more detailed resource estimate and accompanying explanation at a future meeting.

FDA Sentinel Proposal:

FDA restated the importance of this proposal to the continued development of the Sentinel System. Industry reaffirmed their support for the continued development of the Sentinel System. Discussion then shifted to what preparation was needed in order to discuss possible Sentinel commitments at future meeting.

FDA stated that it is preparing answers to questions raised by Industry at a previous meeting about resource needs associated with the proposal. Industry noted that they are preparing a proposal that would address their concerns regarding FDA communications of Sentinel analyses. Industry noted two areas for future discussion: industry access to Sentinel for analyses and communication about lessons learned through use of the Sentinel System. Industry agreed to provide further details at a future

meeting about challenges they have had with Sentinel access. FDA reaffirmed its ongoing efforts to be transparent about the development and use of the Sentinel System, including an annual public workshop and website that includes all deliverables. FDA and Industry agreed to revisit the topic at a future meeting.

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