FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
October 21, 2015: 9:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1211

Purpose

To continue discussion of FDA and Industry post-market proposals.

Participants

FDA		Industry	
Bob Ball	CDER	Beatrice Biebuyck	BIO (Alexion)
Melissa Robb	CDER	Jennifer Boyer	BIO (Alkermes)
Aaron Sherman	CDER	Jeffrey Francer	PhRMA
Terry Toigo	CDER	Kay Holcombe	BIO
Craig Zinderman	CBER	Rob Metcalf	PhRMA (Eli Lilly)

Industry Real World Evidence Proposal:

Industry distributed several case studies demonstrating how real world evidence has been used in the FDA's regulatory decision making process, collected from sponsors. FDA asked a few clarifying questions, and planned to review in more detail. Industry and FDA agreed that these cases could inform the types of questions that need to be asked and methods that need to be developed in order to evaluate the use of real world evidence (RWE) for benefit/risk assessment. FDA noted that it could also be informative to understand the situations where companies tried unsuccessfully to use RWE for benefit/risk assessment; noting that often, one can learn more from failure then success. Industry cited the need for additional public discussion of this topic.

Discussion then shifted to the proposed process. FDA articulated the need for any commitment to be broad enough to allow for the expected progression in the underlying science, while also being specific enough to produce fruitful results. Industry agreed to provide suggestions about what topics might be most helpful to inform future discussions.

FDA Real World Evidence Proposal:

As promised at the previous (October 14th, 2015) meeting, FDA provided greater detail on how Sentinel's resource needs would evolve under its proposal. FDA also discussed the type of expertise needed to support expanded Sentinel capacity and fully integrate Sentinel use into FDA's regulatory review process. FDA stated that the growth of Sentinel capabilities would be slowed in the absence of PDUFA funding to support this activity. Industry inquired about uses of the Sentinel System outside the scope of new drug surveillance. FDA agreed to provide more information on the topic. Further discussion focused on the types of goals that might be considered to measure the progress of Sentinel's expansion. FDA also explained the resource needs of their proposal to explore new sources of RWE (such as social media) for safety.

Agenda for Next Meeting:

In addition to further discussion of FDA and Industry's respective RWE proposals, Industry indicated a desire to discuss enhancing FDA communication of safety issues. FDA and industry decided to revisit the issue at the next meeting. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.