FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
December 15, 2015: 12:30pm-2:30pm
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Purpose

To discuss potential commitments related to FDA's Sentinel proposal.

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	Paula Rinaldi	PhRMA (Novartis)

Summary:

The meeting began with a discussion of the Sentinel proposal's relationship to other proposals being considered by the sub-group and the potential structure of the commitment letter. FDA and Industry agreed to continue discussing this at a future meeting.

FDA gave a short presentation about Sentinel communication and outreach strategies to clarify current practices. The presentation and discussion covered communication activities related to both an individual Sentinel query and general Sentinel outreach and education. This led to a discussion of potential Sentinel proposal goals, including outreach to ensure dissemination of lessons learned from Sentinel use, facilitating broader public access to Sentinel so that others besides FDA can use the resource, and integrating Sentinel into the FDA post-market safety regulatory review process.

Industry reiterated their concern about having adequate time to prepare to address any public inquiries resulting from FDA's public posting of safety information related to their product, including findings from Sentinel. FDA stated that it is considering this concern and is planning to discuss a safety communication proposal at a future meeting.

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