FDA-Industry PDUFA VI Reauthorization Meeting
Post-Market Sub-Group
November 18, 2015: 10:30am-11:30am
FDA White Oak Campus, Silver Spring, MD
Building 32, Room 1227

Purpose

To discuss safety communication issues raised by Industry at a previous meeting.

Participants

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

Background

At this sub-group's October 21st and November 4th 2015 meetings, Industry and FDA discussed the process and timeliness for notifying sponsors when safety issues about their products are identified. The purpose of this meeting was to further discuss these processes to aid in determining if this topic is appropriate for inclusion in ongoing negotiations relating to PDUFA-funded drug safety activities. Three broad topics related to communication about safety issues were discussed: tracked safety issues, 921 postings, and Sentinel analyses.

Summary

FDA explained the current process for notifying sponsors about new tracked safety issues relating to their products. Industry noted issues with the consistency of implementation of FDA's current policy. FDA noted that there is a process improvement effort ongoing related to tracked safety issues, including a review of FDA's process for communicating with sponsors.

Also addressed were notification issues relating to the quarterly posting of safety issues ("921 postings" as mandated by the Food and Drug Administration Amendments Act of 2007, section 921). FDA and Industry discussed the possibility of including this topic in ongoing negotiations, and agreed that it would be important to consider any underlying FDA resource needs. FDA stated that they would explore this further for discussion at a future meeting.

The final topic discussed was communications specific to analyses done through the Sentinel System. FDA explained that its goal is be transparent about the use of the Sentinel System and public posting of information is one way to further that goal. Industry acknowledged this practice. Similar to concerns related to 921 postings and other FDA public dissemination of information about safety issues, Industry explained the importance of advance notice so that the company is prepared to address inquiries from patients, health professionals, and other members of the public. Industry and FDA agreed to explore this topic further at a future meeting.

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