**FDA-Industry PDUFA VI Reauthorization Meeting**
**Post-Market Sub-Group**
**November 4, 2015: 9:30am-11:30am**
**FDA White Oak Campus, Silver Spring, MD**
**Building 32, Room 1333**

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**Purpose**

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

**Participants**

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

**FDA Real World Evidence (Safety) Proposal – New Sources of Data:**

FDA clarified that the goal of this proposal is to determine if newly available sources of data (e.g., social media) may demonstrate value in drug safety surveillance, and if so, how to best and most efficiently process them. FDA and Industry also discussed that a variety of other stakeholders are already conducting research in this area. FDA continued to discuss the potential value of developing the relevant internal expertise for this purpose. Industry stated that they understood the importance of better understanding new sources of safety data, and also indicated that more clarity with regard to which potential sources of safety information have value would be beneficial. Industry requested more information on the resource needs of this proposal over the course of PDUFA VI. FDA agreed to provide more information on the subject. FDA and Industry agreed to continue the discussion.

**Industry Real World Evidence (Efficacy) Proposal – Benefit/Risk Assessment:**

FDA and Industry continued the discussion regarding the potential for FDA to initiate a public stakeholder process to explore how real world evidence (RWE) may be used for benefit/risk assessment, and report on the findings so that there is a clear understanding of the Agency's thinking on this topic. FDA restated the need for any commitment to be broad enough to allow for the expected progression in the underlying science. As an example, FDA noted the varying definitions of RWE. Industry agreed that they did not want to limit the scope of this proposal but stressed a need for consistency across FDA regarding how RWE is considered and used both for safety and efficacy assessments. FDA stated that they understood this need, but also felt it was important to maintain flexibility in the process. FDA and Industry agreed to continue discussing this process at a future meeting.

**FDA Real World Evidence Proposal – Sentinel:**

FDA and Industry discussed the importance of continued development of the Sentinel System, and its value as a safety surveillance tool. Industry expressed concerns about the difficulty of accessing Sentinel data directly. FDA stated that it understands the importance to Industry of being able to access Sentinel

directly to enhance safety monitoring. FDA continued that it hopes that the system can one day be a national resource. FDA suggested that this may not be the appropriate context to continue discussions on Sentinel access. Discussion continued about expanding the breadth of safety issues that Sentinel's ARIA system is able to cover.

Industry also raised concerns about inconsistencies in FDA's communications with Sponsors prior to FDA making public announcements about safety issues concerning a Sponsor's drug. FDA was receptive to their concerns, and agreed to provide more information on the topic at a future meeting.

**Agenda for Next Meeting:**

The meeting was concluded by agreeing to a schedule of topics for future meetings. There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.