Stakeholder Meeting on PDUFA VI Reauthorization  
November 16, 2015, 1:00 PM – 3:00 PM  
FDA White Oak Campus, Silver Spring, MD

**Purpose**  
To continue discussions of the current status of the human drug and biologic review programs in the context of PDUFA reauthorization. Topics for discussion were based on stakeholder perspectives shared at the July 15, 2015 public meeting and docket submissions.

**Participants**

**FDA**
- Bob Ball  
- Steve Berman  
- Patrick Frey  
- Hector Izurieta  
- Andy Kish  
- Theresa Mullin  
- Mary Parks  
- Graham Thompson  
- Terry Toigo

**Registered Stakeholders**
- Cynthia Bens  
- Ron Bartek  
- Paul Brown  
- Ryne Carney  
- Allison Durham  
- Eric Gascho  
- Steve Gibson  
- Rob Goldsmith  
- Lisa Goldstan  
- Amanda Grimm  
- Lori Hoffman  
- Anna Hyde  
- Bennie Johnson  
- Maureen Japha  
- Ethan Jorgensen-Earp  
- Carol Kennedy  
- Ian Kremer  
- Bea Long  
- Andrea Lowe  
- Amanda Pezalla  
- Andrew Sperling  

Alliance for Aging Research  
Friedreich’s Ataxia (FARA)  
National Center for Health Research  
Alliance for Aging Research  
FaegreBD Consulting  
National Health Council  
The ALS Association  
Cancer Support Network  
American College of Cardiology  
Cystic Fibrosis Foundation  
Sarcoma Foundation of America  
Arthritis Foundation  
Juvenile Diabetes Research Foundation  
FasterCures  
American Academy of Pediatrics  
EveryLife Foundation of Rare Diseases  
Leaders Engaged on Alzheimer's Disease  
Environmental Protection Agency (EPA)  
Society for Women’s Health Research  
American Academy of Dermatology Association  
National Alliance on Mental Illness
The meeting on November 16 focused on providing stakeholders an overview and update on postmarket drug safety activities, which had been identified as a top topic of interest to the stakeholders in the previous meeting in September.

**Drug Safety and PDUFA**
FDA began its presentation by providing a brief historical overview of the evolution of drug safety activities in the PDUFA era. PDUFA V (2012) focused on enhancements and modernizations to the drug safety systems, particularly with respect to Risk Evaluation and Mitigation Strategies (REMS) authorized under the Food and Drug Administration Amendments Act of 2007 (FDAAA), Sentinel, and pharmacovigilance processes. Commitments in these areas included public meetings, guidances, reports, tool development, and enhancement projects. FDA provided updates on progress made on these commitments and its plans for continued modernization of the US drug safety system, including: adoption of new scientific approaches; improving the utility of the tools for the detection, evaluation, prevention, and mitigation of adverse events; and enhancing collaboration between pre-market and post-market review staff.

**Post-marketing Drug Safety Monitoring**
FDA provided an overview of four of its core post-market safety areas: pharmacovigilance, pharmacoepidemiology, pharmaceutical risk management, and medication error prevention. FDA provided a detailed introduction to its Sentinel Initiative, begun in 2008 under FDAAA, to establish a postmarket risk identification and analysis system to link and analyze safety data from multiple sources. The future plans for Sentinel were described, including the move from the Mini-Sentinel pilot activities to the sustained active surveillance system and the development of enhanced methodological approaches.

**Case Study: A Claims-based Big Data CMS Study of the High Dose Influenza Vaccine**
FDA presented a case study on the use of the Centers for Medicare and Medicaid Services (CMS) database to examine data on the use of marketed medical products. The case study described the use of data from the CMS database to examine the use of high-dose influenza vaccine in elderly patients, following the accelerated licensure of the vaccine based upon surrogate endpoint trial data. The study also provided FDA experience and analytical methods that may be applicable for the study of other regulated products.

**Question and Answer and Open Discussion**
The Stakeholder discussion session began with technical questions regarding special populations and use of registries in postmarket regulatory activities. The use of user fee funding for observational studies of marketed medical products was discussed, as were plans for additional studies based on CMS data. In response to a stakeholder inquiry about the use of ex-US data in postmarket surveillance, FDA described its work on global regulatory harmonization and, when appropriate, the use of non-US datasets. The session concluded with a discussion of potential biases in observational studies and methods for controlling them.

**Plan for Next Meeting**
The Stakeholder Meeting on PDUFA VI Reauthorization is scheduled for December 17.

**Meeting End Time:** 3:00 PM