Stakeholder Meeting on PDUFA VI Reauthorization
February 19, 2016, 2:00 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.

Participants
FDA
Steve Berman CDER
Amanda Edmonds OC
Patrick Frey CDER
John Jenkins CDER
Chris Joneckis CBER
Andy Kish CDER
Theresa Mullin CDER
Graham Thompson CDER
Terry Toigo CDER
Brad Wintermute OIMT

Registered Stakeholders
Davis Argersinger National Organization for Rare Diseases
Ron Bartek Friedrich’s Ataxia Research Alliance
Cynthia Bens Alliance for Aging Research
Ryne Carney Alliance for Aging Research
Christin Engelhardt National Coalition for Cancer Survivorship
Mark Fleury American Cancer Society Cancer Action Network
Eric Gascho National Health Council
Rob Goldsmith Cancer Support Community
Lisa Goldstein American College of Cardiology
Lori Hoffman Sarcoma Foundation of America
Maureen Japha FasterCures
Bennie Johnson JDRF
Stephanie Krenrich Cystic Fibrosis Foundation
Andrea Lowe Society for Women's Health Research
Sarah Mills Cure SMA
Thair Phillips RetireSafe
Jean Silver-Isenstadt National Physicians Alliance
Andrew Sperling National Alliance on Mental Illness
Kristin Stephenson Muscular Dystrophy Association
Ernest Voyard The Leukemia & Lymphoma Society
The meeting on January 15, 2016 included one presentation by FDA, an update on the Prescription Drug User Fee Act reauthorization, followed by a discussion period.

PDUFA Reauthorization Update and Discussion

FDA provided a presentation on the reauthorization activities to-date and plans for future activities. Negotiations between FDA and representatives from industry, and discussions between FDA and patient and consumer advocate stakeholders, began in September 2015 and concluded in February 2016, with this meeting. The commitments negotiated by FDA and industry representatives need to be ratified and cleared by stakeholders on both sides, at which point a final public meeting will be held to discuss the agreement. The key areas in the FDA-industry discussions were: pre-market review enhancements, regulatory decision tools enhancements, post-market enhancements, information technology enhancements, financial management enhancements, and hiring capacity enhancements.

The pre-market review enhancements discussed were in the areas of NME Review Program 2.0, goal extensions for missing manufacturing facility information, meeting management, FDA-sponsor communication during drug development, early consultations on new surrogate endpoints, combination product review, breakthrough therapies, and rare disease drug development. The regulatory decision tools enhancements discussed were in the areas of enhancing the incorporation of patient’s voice in drug development and decision-making, enhancing benefit-risk assessment in regulatory decision-making, advancing model-informed drug development, enhancing capacity to review complex innovative trial designs, enhancing capacity to support analysis data standards for product development and review, and enhancing drug development tools qualification pathway for biomarkers.

The post-market enhancements discussed were in the areas of timely and effective evaluation and communication of postmarketing safety findings related to new drugs, advancing postmarketing drug safety evaluation through expansion of the Sentinel System and integration into FDA pharmacovigilance activities, and enhancing use of real world evidence for use in regulatory decision-making. The information technology enhancements discussed were in the areas of the electronic submission process, and electronic submission and data standards activities. The financial management enhancements discussed were in the areas of enhancing financial predictability, efficiency, and stability in PDUFA VI; and enhancing management of resources in PDUFA VI. The hiring capacity enhancements discussed were aimed to enhance the ability to hire and retain qualified staff critical to ensuring the availability of new safe and effective drugs.

Meeting End Time: 3:05 PM