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

Meeting Start Time: 2:00 PM

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