Stakeholder Meeting on PDUFA VI Reauthorization
January 15, 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
Chris Joneckis	CBER
Theresa Mullin	CDER
Miranda Raggio	CDER
Graham Thompson	CDER
Terry Toigo	CDER

Registered Stakeholders

James Baumberger	American Academy of Pediatrics
Cynthia Bens	Alliance for Aging Research
Lauren Bloch	Faegre BD Consulting
Ryne Carney	Alliance for Aging Research
Beatriz Duque Long	Epilepsy Foundation
Mark Fleury	American Cancer Society Cancer Action Network
Eric Gascho	National Health Council
Steve Gibson	The ALS Association
Rob Goldsmith	Cancer Support Community
Lisa Goldstein	American College of Cardiology
Amanda Grimm	Cystic Fibrosis Foundation
Lori Hoffman	Sarcoma Foundation of America
Anna Hyde	Arthritis Foundation
Maureen Japha	FasterCures
Bennie Johnson	JDRF
Annie Kennedy	Parent Project Muscular Dystrophy
Madeleine Konig	American Heart Association
Marina Kozak	Friends of Cancer Research
Ian Kremer	LEAD Coalition
Jeffrey Last	Alzheimer's Association
Andrea Lowe	Society for Women's Health Research
Paul Melmeyer	National Organization for Rare Disorders
Sarah Mills	DPG - Cure SMA
Elisabeth Nugent	National Organization for Rare Disorders
Samantha Roberts	Friends of Cancer Research
Tracy Rupp	National Center for Health Research

Michael Shea	Friends of Cancer Research
Travis Smith	ALS Association
Kristin Stephenson	Muscular Dystrophy Association (MDA)
Timothy Swope	Bipartisan Policy Center
Laura Thornhill	Alzheimer's Association
Ernest Voyard	The Leukemia & Lymphoma Society
John Wylam	National MS Society

Meeting Start Time: 2:00 PM

The meeting on January 15, 2016 included two presentations by FDA, one an overview of the Breakthrough Therapy Designation Program, and the other an update on the Prescription Drug User Fee Act reauthorization.

Overview of the Breakthrough Therapy Designation Program

FDA presented an overview of FDA's expedited drug development and review programs, focusing on the Breakthrough Therapy Program. Designation as a Breakthrough Therapy expedites both the development and the review of a drug or biologic. Section 506(a) of the Federal Food, Drug, and Cosmetic Act provides for designation of a drug as a breakthrough therapy if the drug: 1) is intended to treat a serious or life threatening disease or condition, and 2) has preliminary clinical evidence that indicates that it may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. FDA, after noting that CBER follows similar processes as CDER, described CDER's procedure for the review of Breakthrough Designation Requests and the procedures by which a breakthrough designation speeds drug development and review. FDA reviewed the data of the Breakthrough Program's usage since 2012, listed examples of its successes in bringing needed drugs to market quickly, and discussed the resource burden incumbent on the program and the Centers.

PDUFA Reauthorization Update

FDA provided a brief status update as the reauthorization process as negotiation meetings with industry near completion. The areas identified as major areas for enhancement are: administrative enhancements to ensure the long-term stability of the program (hiring and financial), pre-market review, regulatory decision tools, and post-market safety. FDA provided brief descriptions of the enhancements that have been discussed in each of these areas and reviewed the plans for progressing towards statutory reauthorization.

Plan for Next Meeting
The Stakeholder Meeting on PDUFA VI Reauthorization is scheduled for February 19th at 1:30pm.

Meeting End Time: 3:00 PM