Stakeholder Meeting on PDUFA VI Reauthorization
December 17, 2015, 1:30 PM – 3:30 PM
FDA White Oak Campus, Silver Spring, MD

Purpose

To continue discussions of the human drug and biologic review programs in the context of PDUFA reauthorization.

Participants

FDA

Jill Adleberg	OC
Steve Berman	CDER
Amanda Edmonds	OC
Patrick Frey	CDER
John Jenkins	CDER
Chris Joneckis	CBER
Andy Kish	CDER
Theresa Mullin	CDER
Mary Parks	CDER
Graham Thompson	CDER
Terry Toigo	CDER

Registered Stakeholders

James Baumberger	American Academy of Pediatrics
Cynthia Bens	Alliance for Aging Research
Lauren Bloch	FaegreBD Consulting
Marc Boutin	National Health Council
Ryne Carney	Alliance for Aging Research
Charles Cascio	American College of Cardiology
Christin Engelhardt	National Coalition for Cancer Survivorship
Brian Fiske	Epilepsy Foundation
Mark Fleury	American Cancer Society Action Network
Eric Gascho	National Health Council
Rob Goldsmith	Cancer Support Community
Amanda Grimm	Cystic Fibrosis Foundation
Anna Hyde	Arthritis Foundation
Maureen Japha	FasterCures
Ethan Jorgensen-Earp	American Academy of Pediatrics
Annie Kennedy	Parent Project Muscular Dystrophy
Madeleine Konig	American Heart Association
Rachel Koren	Cystic Fibrosis Foundation
Ian Kremer	Leaders Engaged on Alzheimer's Disease (LEAD) Coalition
Stephanie Krenrich	Cystic Fibrosis Foundation

Jeffrey Last	Alzheimer's Association
Andrea Lowe	Society for Women's Health Research
Janet Marchibroda	Bipartisan Policy Center
Rebecca McGrath	District Policy Group/Cure SMA
Paul Melmeyer	NORD
Angela Ostrom	Epilepsy Foundation
Tracy Rupp	National Center for Health Researcg
Andrew Sperling	National Alliance on Mental Illness (NAMI)
Timothy Swope	Bipartisan Policy Center
Laura Thornhill	Alzheimer's Association
Ernest Voyard	The Leukemia & Lymphoma Society
Patrick Wildman	The ALS Association
Cynthia Bens	Alliance for Aging Research
Ron Bartek	Friedreich's Ataxia (FARA)
Paul Brown	National Center for Health Research
Ryne Carney	Alliance for Aging Research
Allison Durham	FaegreBD Consulting
Eric Gascho	National Health Council
Steve Gibson	The ALS Association
Rob Goldsmith	Cancer Support Network
Lisa Goldstan	American College of Cardiology
Amanda Grimm	Cystic Fibrosis Foundation
Lori Hoffman	Sarcoma Foundation of America
Anna Hyde	Arthritis Foundation
Bennie Johnson	Juvenile Diabetes Research Foundation
Maureen Japha	FasterCures
Ethan Jorgensen-Earp	American Academy of Pediatrics
Carol Kennedy	EveryLife Foundation of Rare Diseases
Ian Kremer	Leaders Engaged on Alzheimer's Disease
Bea Long	Environmental Protection Agency (EPA)
Andrea Lowe	Society for Women's Health Research
Amanda Pezalla	American Academy of Dermatology Association
Andrew Sperling	National Alliance on Mental Illness
Joseph Stewart	Health and Medicine Counsel of Washington
Jennifer Tripp	Muscular Dystrophy Association
Ernest Voyard	The Leukemia & Lymphoma Society, Office of Public Policy
Patrick Wildman	The ALS Association
John Wylam	National MS Society

Meeting Start Time: 1:30 PM

The meeting on December 17 began with a period of stakeholder presentations on topics of interest for PDUFA VI and concluded with an FDA presentation of the status of negotiations at the midpoint including topics of interest to both industry and FDA.

Stakeholder Presentations and Discussion

The following stakeholder organizations presented on topics related to the PDUFA VI reauthorization priorities, process, and comments:

Alliance for Aging Research
Bipartisan Policy Center
Cancer Support Community
Cure SMA
Cystic Fibrosis Foundation
FasterCures
Leaders Engaged on Alzheimer's Disease
National Alliance on Mental Illness
National Coalition for Cancer Survivorship
National Health Council
Parent Project Muscular Dystrophy (PPMD)
Society for Women's Health Research

Common themes in many of the presentations centered on enhancing inclusion of patient voice throughout the drug development process and ensuring that the FDA has adequate resources to recruit and retain staff qualified to execute drug review processes in light of emerging science. Other topics discussed included biomarker qualification; the review of combination products; and the design of clinical trials and the drug review process to be more responsive to the needs of patients, including patient subgroups.

PDUFA Reauthorization Mid-Course Update

FDA provided a brief status update as the reauthorization process nears its midpoint. 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.

Plan for Next Meeting
The Stakeholder Meeting on PDUFA VI Reauthorization is scheduled for January 15, 2016.

Meeting End Time: 3:30 PM