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
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