Stakeholder Meeting on PDUFA VI Reauthorization
September 28, 2015, 1:30 PM – 3:05 PM
FDA White Oak Campus, Silver Spring, MD

Purpose
To discuss the current status of the human drug and biologic review programs, review stakeholder perspectives shared at the July 15, 2015 public meeting and docket submissions, and plan topics for future stakeholder discussions.

Participants

FDA
Josh Barton  CDER
Steve Berman  CDER
Amanda Edmonds  OC
John Jenkins  CDER
Chris Joneckis  CBER
Andrew Kish  CDER
Theresa Mullin  CDER
Mary Parks  CDER
Grail Sipes  CDER
Graham Thompson  CDER
Terry Toigo  CDER
Brad Wintermute  OIMT

Registered Stakeholders
Jeffrey Anders  Lupus and Allied Diseases Association
Cynthia Bens  Alliance for Aging Research
Marc Boutin  National Health Council
Paul Brown  National Center for Health Research
Allyson Browne  Patient
Ryne Carney  Alliance for Aging Research
Diane Dorman  dD Consulting
Christin Engelhardt  National Coalition for Cancer Survivorship
Stephanie Fischer  EveryLife Foundation for Rare Diseases
Mark Fleury  American Cancer Society Cancer Action Network, Inc.
Kara Gainer  Cure SMA (Spinal Muscular Atrophy)
Eric Gascho  National Health Council
James Gelfand  March of Dimes Foundation
Rob Goldsmith  Cancer Support Network
Lisa Goldstein  American College of Cardiology
Tamar Haro  American Academy of Pediatrics
Anna Hyde  The Arthritis Foundation
Maureen Japha  FasterCures
Bennie Johnson  Juvenile Diabetes Research Foundation
Meeting Start Time: 1:30 PM

Welcome and FDA Introductions
FDA began the meeting by welcoming stakeholders and discussing the purpose of these meetings as part of the reauthorization provisions as specified in statute. These monthly meetings are meant to continue the discussions of stakeholder perspectives that began at the July 15, 2015 public meeting. Reauthorization of PDUFA focuses on enhancements to the drug review process, not FDA policy.

Background on PDUFA and Review of Stakeholder Perspectives
FDA provided a brief historical perspective on user fee legislation for prescription drugs and highlighted the commitments and goals incumbent upon FDA as a result of PDUFA V. FDA reviewed its performance related to the metric goals and commitments and commented on the successes achieved. FDA offered perspective on some environmental challenges facing its operations, such as funding uncertainties, unfunded mandates, and the difficulty it faces in hiring and retaining qualified regulatory professionals. A review of perspectives on PDUFA VI by patient advocates, consumer advocates, healthcare professionals and academics, and representatives from regulated industry shared at the July 15, 2015 public meeting and in the docket was presented.

Stakeholder Introductions and Topics
A representative from each stakeholder organization offered an introduction and highlighted their group’s primary topics pertaining to the PDUFA VI renegotiation. Key themes echoed by stakeholders centered on continuing to involve patient voice in drug development, ensuring
that the FDA has adequate resources to recruit and retain qualified staff, and improving methods for including biomarkers and advanced clinical trial designs in drug development and regulation.

Wrap-Up and Overview of Future Meetings
Based on the topic summary categories identified by the FDA, stakeholders were asked to indicate their preference for the order in which the subject areas would be addressed in future meetings. Advancing the science of patient engagement was selected as the preferred topic for the next stakeholder meeting. Regulatory science and trial design, enhanced postmarket signal monitoring, and ensuring continued FDA performance were selected, in order, for subsequent meetings.

Meeting End Time: 3:05 PM