Patient and Consumer Stakeholder Meeting on MDUFA IV Reauthorization
July 28, 2016, 9:00 – 10:00 AM
FDA White Oak Campus, Silver Spring, MD
Building 31, Great Room Section C

Purpose
To provide a status update on the ongoing MDUFA IV negotiations, plan for future stakeholder meetings and provide clarification of the current proposals.

Participants
FDA

Malcolm Bertoni	Office of the Commissioner (OC)
Marc Caden	Office of Chief Counsel (OCC)
Jonette Foy	Center for Devices and Radiological Health (CDRH)
Don St. Pierre	CDRH
Louise Howe	OCC
Aaron Josephson	CDRH
Sheryl Kochman	Center for Biologics Evaluation and Research (CBER)
Thinh Nguyen	Office of Combination Products (OCP)
Geeta Pamidimukkala	CDRH
Prakash Rath	Office of Legislation (OL)
Darian Tarver	OC
Shannon Thor	OC
Jacquline Yancy	CDRH
Barb Zimmerman	CDRH

Stakeholders

Cynthia Bens	Alliance for Aging Research
Paul Brown	National Center for Health Research
Victoria Burack	Consumers Union
Ryne Carney	Alliance for Aging Research
Vizma Carver	Carver Global Health Group LLC
Diane Dorman	dDConsulting
Beatriz Duque Long	Epilepsy Foundation
Eric Gascho	National Health Council
Lisa Goldstein	American College of Cardiology
Marisol Goss	AAOS
Tamar Haro	American Academy of Pediatrics
Ben Hewitt	ACC (intern)
Maureen Japha	FasterCures
Bennie Johnson	JDRF
Joshua Lorenz	JDRF (intern)
Andrea Lowe	Society for Women's Health Research

Anqi Lu	Pew Charitable Trusts
Paul Melmeyer	National Organization for Rare Disorders
Ben Moscovitch	Pew Charitable Trusts
Andrew Sperling	National Alliance on Mental Illness
Jessica Tyson	Avalere Health
Ernest Voyard	Leukemia & Lymphoma Society
Jeffrey Wojton	Research!America
Jessica Yozwiak	National Organization for Rare Disorders

Meeting Start Time: 9:00 am

FDA welcomed stakeholders and briefly reiterated the role of stakeholder input during MDUFA negotiations.
FDA provided an overview of the most recently published FDA/Industry negotiation meeting minutes from May 16, 2016, and stated that there were no new meeting minutes available because the most recent FDA/Industry negotiation meeting was held only two days earlier, on July 26, 2016.

FDA discussed the current status of proposals
FDA reported that since the May 16th meeting, at which FDA presented a counter proposal package that included low and high options in performance and/or cost for many of the elements of the proposal, there have been some teleconference meetings and small working group calls with Industry. FDA stated that Industry provided a counter proposal on June 9, 2016 that laid out a level of performance and cost that Industry was willing to pay. However, FDA concluded that the costs Industry included in their counter proposal were not congruent with the true cost for the performance levels included. Following receipt of Industry's counter proposal, FDA and Industry had discussions on a best path forward and on July 15, 2015, FDA provided Industry a package priced at the true cost for Industry's desired level of performance, along with other commitments for the program.

FDA provided a general overview of the July 26, 2016 FDA/Industry negotiation meeting. At that meeting, FDA communicated to Industry that FDA can design performance goals to meet Industry's budget or FDA can design a program that includes Industry's desired performance, but that may be in excess of Industry's desired budget. FDA stated that it provided options for Industry to consider as a result of new information impacting proposals related to information technology. Industry renewed concerns about the total cost of the program. FDA explained that its package will provide the capacity to make the program more robust, resilient, consistent and predictable.

FDA provided a general timeline for the rest of the negotiations that included the scheduling of the public meeting to review the draft recommendations.

FDA addressed clarifying questions from the stakeholders
FDA answered questions related to the status of the Real World Evidence (RWE) proposal. FDA explained that the scope of the RWE proposal has not changed although FDA has reduced

the cost of the RWE proposal by ramping up funding that would be passed to the National Evaluation System for health Technology (NEST) Coordinating Center over the course of MDUFA IV.

FDA answered questions related to parity between and impact of the patient preference, patient reported outcomes, and combination products content included in the PDUFA commitment letter and the proposals put forth in the MDUFA IV negotiations. FDA explained that MDUFA IV negotiations have not included discussion of a combination products proposal. FDA explained that the PDUFA agreement recently reached between FDA and the drug industry includes a proposal on combination products that includes FTEs for CDRH. FDA further explained that there has been an Agency-wide effort to look at our processes and coordinate across centers with respect to combination products. The size and cost of the MDUFA IV proposal for patient engagement is modest compared to PDUFA.

The next patient and consumer stakeholder meeting is scheduled for August 25, 2016.

End: 10:01am