Public Meeting on Prescription Drug User Fee Act (PDUFA) Reauthorization

July 15, 2015

8:00 – 9:00 am **Registration**

9:00 – 9:05 am **Welcome**

Terry Toigo, Center for Drug Evaluation and Research, FDA
Meeting Moderator & Associate Director for Drug Safety Operations

9:05 – 9:15 am **Opening Remarks**

Stephen Ostroff, FDA
Acting Commissioner of Food and Drugs

Robert Califf, FDA
Deputy Commissioner for Medical Products and Tobacco

9:15 – 9:30 am **PDUFA Background and Reauthorization Process**

Theresa Mullin, Center for Drug Evaluation and Research, FDA
Director, Office of Strategic Programs

9:30 – 9:50 am **Panel 1 – Consumer Perspectives**

Allan Coukell, Pew Charitable Trusts
Senior Director for Health Programs

Sally Greenberg, National Consumers League
Executive Director

9:50 – 10:40 am **Panel 2 – Patient Perspectives**

Paul Melmeyer, National Organization for Rare Disorders
Associate Director of Public Policy

Marc Boutin, National Health Council
Chief Executive Officer

Jeff Allen, Friends of Cancer Research
Executive Director

Cynthia Bens, Alliance for Aging Research
Vice President of Public Policy

Maureen Japha, Milken Institute and FasterCures
Legal Counsel and Associate Director for IP

10:40 – 10:55 am **Break**

10:55 – 11:25 am **Panel 3 - Health Care Professionals Perspectives**

Stacie Maass, American Pharmacists Association
Senior Vice President, Pharmacy Practice and Government Affairs

James Baumberger, American Academy of Pediatrics
Assistant Director, Department of Federal Affairs

Richard J. Kovacs, American College of Cardiology
Professor of Clinical Medicine, Indiana University School of Medicine

11:25 – 11:55 am **Panel 4 – Regulated Industry Perspectives**

Sascha Haverfield, Pharmaceutical Research and Manufacturers of America
Vice President for Scientific and Regulatory Affairs

Kay Holcombe, Biotechnology Industry Organization
Senior Vice President for Science Policy

Michael Werner, Alliance for Regenerative Medicine
Partner, Holland & Knight

11:55 – 12:45 pm **Lunch**

12:45 – 1:15 pm **Panel 5 – Scientific and Academic Expert Perspectives**

Greg Daniel, Center for Health Policy, Brookings Institution
Managing Director for Evidence Development and Innovation

Daniel Carpenter, Harvard University
Professor of Government

&

Aaron Kesselheim, Harvard Medical School
Associate Professor of Medicine

Ernst Berndt, Massachusetts Institute of Technology
Professor of Applied Economics

&

Rena Conti, University of Chicago
Assistant Professor of Health Policy and Economics

1:15 – 1:30 pm **Closing Remarks**

Janet Woodcock, Center for Drug Evaluation and Research, FDA
Center Director

1:30 – 2:00 pm **Open Public Comment**