



Public Meeting on Patient-Focused Drug Development



October 25, 2012

8:30 – 9:00 am	Registration
9:00 – 9:05 am	Welcome Patrick Frey <i>Director, Office of Planning and Analysis, FDA</i>
9:05 – 9:15 am	Opening Remarks Janet Woodcock, MD <i>Director, Center for Drug Evaluation and Research, FDA</i>
9:15 – 9:30 am	Patient-Focused Drug Development Overview Theresa Mullin, PhD <i>Director, Office of Planning and Informatics, FDA</i>
9:30 – 10:00 am	Panel: FDA Perspectives John Jenkins, MD <i>Director, Office of New Drugs</i> Donna Griebel, MD <i>Director, Division of Gastroenterology and Inborn Errors Products</i> Patricia Keegan, MD <i>Director, Division of Oncology Products II</i> Theresa Michele, MD <i>Team Lead, Division of Pulmonary, Allergy, and Rheumatology Products</i> Ginette Michaud, MD <i>Deputy Director, Office of Blood Research and Review, Center for Biologics Evaluation and Research</i>
10:00 – 10:15 am	Break
10:15 – 11:15 am	Open Public Comment: Disease Area Nominations
11:15 – 11:45 am	Panel: Incorporating Patient Perspectives Anne Pariser, MD <i>Associate Director for Rare Diseases, Office of New Drugs, FDA</i> Megan O’Boyle <i>Patient Advocate, Phelan-McDermid Syndrome Foundation</i> Jason Lundy, PhD <i>Assistant Director, Patient-Reported Outcome Consortium, Critical Path Institute</i>
11:45 am – 12:15 pm	Open Public Comment: Incorporating Patient Perspectives
12:15 – 12:30 pm	Wrap Up