Stakeholder Input – BPCA & PREA

Public Meeting

March 25, 2015

9:00 – 9:05 am	**Welcome and Opening Remarks** Jill Warner, JD *Office of Special Medical Programs, OC, FDA*
9:05 – 9:30 am	**Overview: Labeling Advances & International and Scientific Successes** Dianne M. Murphy, MD *Office of Pediatric Therapeutics, OC, FDA*
9:30 – 10:00 am	**Implementation of BPCA/PREA: Ecstasy & Agony** **PeRC, PSP, waivers, deferrals, transparency** Lynne Yao, MD *Division of Pediatric and Maternal Health, CDER, FDA*
10:00 – 10:15	**Biologics Update** Barbara Buch, MD *Office of the Center Director, CBER, FDA*
10:15 – 10:30	**NIH-FDA Pediatric Drug Development Process** Anne Zajicek, MD, PharmD *National Institute of Child Health and Human Development, NIH*
10:30 – 10:45 am	**Break**
10:45 – 12:00 am	**Stakeholder Questions and Comments**
12:00 – 1:00 pm	**Lunch**
1:00 – 1:30 pm	**Scientific Challenges and the Future** Neonatology – Robert "Skip" Nelson, MD, PhD *Office of Pediatric Therapeutics, OC, FDA* Rare Diseases – Acting Director *Rare Diseases Program, OND, CDER, FDA* Oncology – Greg Reaman, MD *Office of Hematology and Oncology Products, CDER, FDA*
1:30 – 2:30 pm	**Stakeholder Questions and Comments**
2:30 – 2:45 pm	**Break**

Stakeholder Input – BPCA & PREA

Public Meeting

March 25, 2015

2:45 – 3:15 pm	**Scientific Challenges and the Future (cont.)** Extrapolation – Dianne Murphy, MD *Office of Pediatric Therapeutics, OC, FDA* Validating Endpoints in Pediatrics – Susan McCune, MD *Office of Translational Sciences, CDER, FDA* Pediatric Networks – Daniel Benjamin, MD, PhD *Duke Clinical Research Institute*
3:15 – 4:15 pm	**Stakeholder Questions and Comments**
4:15 – 4:30 pm	**Closing Remarks –** TBD (Dr. Califf invited)