

Joint Meeting of the Pediatric Advisory Committee and the Pediatric Ethics Subcommittee
 Thursday, May 18, 2017
 FDA White Oak Great Room (Building 31)
 10903 New Hampshire Avenue
 Silver Spring, MD 20993

8:30 AM	Welcome and Introductions	Mark Hudak, MD Chair, Pediatric Advisory Committee (PAC)
8:40 AM	Opening Statement	Marieann R. Brill, MBA, RAC, MT(ASCP) Designated Federal Official, PAC Office of Pediatric Therapeutics (OPT), Office of the Commissioner (OC), FDA
8:45 AM	Review of Agenda	Robert "Skip" Nelson, MD, PhD Deputy Director and Senior Pediatric Ethicist, OPT/OC/FDA
8:50 AM	FDA Presentation	Donna Snyder, MD Pediatric Ethicist, OPT/OC/OPT
9:20 AM	UCLA Principle Investigator Presentation	Perry Shieh, MD, PhD Associate Professor & Director of the Neuromuscular Program, Department of Neurology, David Geffen School of Medicine, UCLA
9:50 AM	UCLA IRB Presentation	James McGough, MD Professor of Clinical Psychiatry, Semel Institute for Neuroscience and Human Behavior, and David Geffen School of Medicine, UCLA
10:20 AM	Parent and Patient Presentation	Brett Bullers, Erin Bullers, and Nicholas Bullers
10:40 AM	Break	
11:00 AM	Open Public Hearing	
12:30 PM	Lunch	
1:30 PM	Sponsor Presentation	Sarepta Therapeutics (TBD)
2:00 PM	Presentation of Questions to the Committee	Robert "Skip" Nelson, MD, PhD Deputy Director, OPT/OC/FDA
2:15 PM	Committee Discussion	Mark Hudak, MD Chair, Pediatric Advisory Committee
3:45 PM	Break	
4:00 PM	Committee Discussion and Vote	Mark Hudak, MD Chair, Pediatric Advisory Committee
5:30 PM	Adjournment	Mark Hudak, MD Chair, Pediatric Advisory Committee