MINUTES OF THE PEDIATRIC ADVISORY COMMITTEE (PAC)

The public meeting was convened 8:30 a.m. to 3:30 p.m., September 20, 2018

Members Present (Voting)	
Robert Dracker, MD, MHA, MBA, CPI (*Chair)* Premchand Anne, MD, MBA, MPH, FACC David Callahan, MD Mary Cataletto, MD, FAAP Randall Flick, MD, MPH Peter Havens, MD, MS Sarah Hoehn, MD, MBe, FAAP Bridgette Jones, MD, MSc, FAAAAI, FAAP Randi Oster, MBA Wael Sayej, MD Christy Turer, MD, MHS, FAAP, FTOS Kelly Wade, MD, PhD	**Temporary Voting Members (Voting Consultants)** James McGough, MD Peggy DiCapua **Non-Voting Members** Ronald Portman, MD, FAAP **Designated Federal Official (DFO)** Marieann Brill, MBA, RAC, MT (ASCP)

U.S. Food and Drug Administration (FDA) Participants

Office of Pediatric Therapeutics	**CDER OSE**:	**CDER OGD**
Susan McCune, MD Judith Cope, MD, MPH LCDR Kenneth Quinto, MD, MPH **CDER DPMH** John Alexander, MD, MPH Ethan Hausman, MD Mona Khurana, MD Amy Taylor, MD, MHS	Steven Bird, PharmD, PhD Vicky Chan, PharmD Carmen Cheng, Pharm D Kate Gelperin, MD, MPH Ivone Kim, MD Cindy Kortepeter, PharmD Robert Levin, MD Shekhar H. Mehta, PharmD, MS Courtney Suggs, PharmD, MPH Peter Waldron, MD	Howard Chazin, MD, MBA **CDER OND** Anthony Fotenos, MD, PhD Robert Lim, MD Marc Stone, MD David Miller **CDER OTS:** Olanrewaju Okusanya, PharmD, MS

Welcome and Introductory Remarks

- Robert Dracker, Chair, Pediatric Advisory Committee
- Marieann Brill, Designated Federal Officer (DFO), read the usual, customary, and required conflict of interest statement.

Office of Pediatric Therapeutics:

- Susan McCune, Director, Office of Pediatric Therapeutics – provided a personnel update, a description of the publicly available information on the status of the STRIDER trial for sildenafil, an update on the Advancing the Development of Pediatric Therapeutics (ADEPT) 5 Workshop held in September, and a description of the publicly available information on CBER and CDER non-compliance letters.
- Judith Cope, Safety Team Lead, Office of Pediatric Therapeutics – provided an update on FDA's ongoing analysis and review of neuropsychiatric adverse events with montelukast and a description of the updated labeling for Noxafil**,** an antifungal product which previously went to the PAC**.**

Open Public Hearing

An opening statement was read by Dr. Dracker, Chair.

One presentation was given by Dr. Srinivasan, National Center for Health Research regarding safety and efficacy of Lexapro in the pediatric population under twelve years of age. She also suggested a Black Box warning be added to the Intuniv label regarding the risk of aggression, suicidality, and homicidality and she stated that other treatments may be better.

Center for Drug Evaluation and Research (CDER):

Standard Review of Adverse Event Presentations

- **Lexapro – Courtney Suggs, PharmD, MPH**

  In addition to the Safety and Utilization Review, the PAC also discussed FDA's recommendation for posting pediatric reviews without new risks or potential safety signals on the web in the future, and asked, "What are the Committee's thoughts about web posting future reviews without new risks or potential safety signals, such as this current review?"

  Two additional presentations regarding generic drugs were included in the review presentation.
  - Drug Ineffective Postmarketing Reports in Drug Safety Surveillance – Cindy Kortepeter, PharmD
  - Generic Drug Development and Safety Evaluation – Howard Chazin, MD, MBA

  The PAC discussed Pediatric Safety Review which concluded that there were no new safety concerns. The PAC concurred with the FDA plan to continue ongoing post-marketing safety monitoring. (vote Yes - 11; No - 1; Abstained - 0)

- **Intuniv (guanfacine ER) – Amy Taylor, MD, MHS**

  The PAC discussed and concurred with the FDA plan to continue ongoing post-marketing safety monitoring to include: monitoring for suicidal ideation and behavior; pancreatic; and medication error involving name confusion. (vote Yes - 11; No - 1; Abstained - 0)

- **Exjade (deferasirox) (no vote) – Peter Waldron, MD; Olanrewaju Okusanya, PharmD, MS; Mona Khurana, MD; Steven Bird, PharmD, PhD; Kate Gelperin, MD, MPH**

  FDA presented the tracked safety issue and further analyses that were conducted over the past three years that led to recent labeling changes and health communications. This was in follow up to the request made at the September 2015 PAC meeting following a family's report of a child with thalassemia who died of fever and dehydration after receiving Exjade.

Updates (no vote)

- **Update on the Safety of Long Acting Beta Agonists (LABAs) – Robert Lim, MD**
- **Update on the FDA Approach to Safety Issue of Gadolinium Retention After Administration of Gadolinium-based Contrast Agents – Anthony Fotenos, MD, PhD**

Adjournment

Robert Dracker, MD, MHA, MBA, CPI, Chair

These summary minutes for the September 20, 2018 meeting of the PAC were approved on October 12, 2018.

I certify that I attended the September 20, 2018 meeting of the Pediatric Advisory Committee and that these minutes accurately reflect what transpired.

/s/	**/s/**
Marieann Brill, MBA, RAC, MT (ASCP) Designated Federal Officer, PAC	Robert Dracker, MD, MHA, MBA, CPI Chair, PAC