

FOOD AND DRUG ADMINISTRATION (FDA)

Office of the Commissioner (OC)

Joint Meeting of the Pediatric Advisory Committee (PAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)

10903 New Hampshire Avenue, Silver Spring, MD

September 26, 2019

FINAL AGENDA

The committees will discuss the pediatric-focused safety review for OxyContin (oxycodone hydrochloride) extended-release tablets, as mandated by the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), and to discuss pediatric data considerations for opioid analgesics labeling and Pediatric Research Equity Act studies for opioids generally, using Opana IR as an example.

9:00 a.m.	Call to Order and Introduction of Committee	Kelly Wade, MD Chairperson, PAC
	Conflict of Interest Statement	Marieann R. Brill, MBA, RAC, MT(ASCP) Designated Federal Officer Pediatric Advisory Committee (PAC) OPT, Office of Clinical Policy and Programs (OCPP) Office of the Commissioner (OC), FDA
	FDA Opening Remarks	Susan McCune, MD Director OPT, OCPP, OC, FDA
9:15 a.m.	American Academy of Pediatrics (AAP) Presentation: Prescription Opioids in Children: Importance of Accurate Labeling and Treatment of Pain	Jennifer Foster, MD, MPH Department of Pediatrics Baylor College of Medicine American Academy of Pediatrics, Member, Committee on Drugs
9:45 a.m.	Pediatric Pain and the Approach to Studying Opioid Analgesics in Pediatric Populations	Joshua Lloyd, MD Clinical Team Leader Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), Office of Drug Evaluation II, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER), FDA
10:22 a.m.	Pediatric Utilization Patterns of Opioid Analgesics, 2009-2018	Ibrahim T. Ibrahim, PharmD, MPH, BCPS Drug Utilization Data Analyst Division of Epidemiology II Office of Surveillance and Epidemiology (OSE) CDER, FDA
10:53 a.m.	BREAK	

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FINAL AGENDA (cont.)

11:11 a.m. Prescription Opioid Abuse and Related Outcomes in the Pediatric Population

Christina R. Greene, PhD
Epidemiologist, Drug Abuse Team II
Division of Epidemiology II
OSE, CDER, FDA

11:27 a.m. Clarifying Questions/Discussions

12:00 p.m. **LUNCH**

1:00 p.m.-
2:00 p.m. **OPEN PUBLIC HEARING**

1:11 p.m. Clarifying Questions/Discussions

1:41 p.m. Presentation of Oxycontin Safety Reviews

- Pediatric Utilization Patterns of Single-Ingredient Oxycodone (Extended Release and Immediate Release), 2013 – 2018
- Pediatric Focused Safety Review: Oxycontin (oxycodone hydrochloride extended-release)

Daniel Bak, PharmD
Drug Utilization Data Analyst
Division of Epidemiology II
OSE, CDER, FDA

Chaitali Patel, PharmD, BCPS
Safety Evaluator
Division of Pharmacovigilance II
OSE, CDER, FDA

2:30 p.m. Opioid Analgesics: Translating Pediatric Study Results into Labeling

Joshua Lloyd, MD
Clinical Team Leader
DAAAP
Office of Drug Evaluation II,
OND, CDER, FDA

3:06 p.m. **BREAK**

3:20 p.m. Committee Discussion and Vote

5:05 p.m. **ADJOURNMENT**

Kelly Wade, MD,
Chairperson, PAC