**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.

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<thead>
<tr>
<th>Time</th>
<th>Event</th>
<th>Presenter</th>
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<tr>
<td>9:00 a.m.</td>
<td>Call to Order and Introduction of Committee</td>
<td>Kelly Wade, MD</td>
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<td>Conflict of Interest Statement</td>
<td>Marieann R. Brill, MBA, RAC, MT(ASCP)</td>
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<td>FDA Opening Remarks</td>
<td>Susan McCune, MD</td>
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<td>Pediatric Pain and the Approach to Studying Opioid Analgesics in Pediatric Populations</td>
<td>Joshua Lloyd, MD</td>
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<td>10:22 a.m.</td>
<td>Pediatric Utilization Patterns of Opioid Analgesics, 2009-2018</td>
<td>Ibrahim T. Ibrahim, PharmD, MPH, BCPS</td>
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<td>10:53 a.m.</td>
<td>BREAK</td>
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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  
  Daniel Bak, PharmD  
  Drug Utilization Data Analyst  
  Division of Epidemiology II  
  OSE, CDER, FDA

- Pediatric Focused Safety Review: Oxycontin (oxycodone hydrochloride extended-release)  
  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