

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the  
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***

Tommy Douglas Conference Center  
10000 New Hampshire Avenue, Silver Spring, Maryland  
March 13-14, 2017

**AGENDA**

---

*The committees will be asked to discuss safety issues for new drug application (NDA) 201655, OPANA ER (oxymorphone hydrochloride) Extended-release Tablets, by Endo Pharmaceuticals Inc., with the indication of management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is an approved extended-release (ER) formulation intended to have abuse-deterrent properties based on its physicochemical properties, however, this information is not currently reflected in product labeling. The committees will be asked to discuss pre- and post-marketing data about the abuse of OPANA ER, and the overall risk-benefit of this product. The committees will also discuss abuse of generic oxymorphone ER and oxymorphone immediate-release (IR) products.*

---

**Day 1: Monday, March 13, 2017**

9:15 a.m.	Call to Order and Introduction of Committee	<b>Almut Winterstein, RPh, PhD, FISPE</b> Chairperson, DSaRM
9:20 a.m.	Conflict of Interest Statement	<b>Stephanie L. Begansky, PharmD</b> Designated Federal Officer, AADPAC
9:25 a.m.	FDA Introductory Remarks	<b>Judy Staffa, PhD, RPh</b> Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
9:30 a.m.	<b>INDUSTRY PRESENTATIONS</b>	<b>Endo Pharmaceuticals Inc.</b>
	Introduction	<b>Harris Rotman, PhD</b> Vice President, US Regulatory Affairs Endo Pharmaceuticals Inc.
	Pain, Opioid Therapy, and Personalized Medicine	<b>Perry G. Fine, MD</b> Professor of Anesthesiology University of Utah
	Decision-Making with Incomplete Observational Data	<b>Alexander M. Walker, MD, DrPH</b> Principal World Health Information Science Consultants
	Post-Marketing Safety and Observational Data: Category 4 Abuse Epidemiology	<b>Neil Shusterman, MD</b> Chief Medical Officer Endo Pharmaceuticals Inc.
	Epidemiology of Opana ER in Context	<b>Richard C. Dart, MD, PhD</b> RADARS® System Rocky Mountain Poison & Drug Center Professor, University of Colorado

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the  
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)*  
March 13-14, 2017

**AGENDA (cont.)**

---

11:00 a.m.	<b>BREAK</b>	
11:15 a.m.	Clarifying Questions	
12:00 p.m.	<b>LUNCH</b>	
1:00 p.m.	<b>FDA PRESENTATIONS</b>	
	Overview	<b>Judy Staffa, PhD, RPh</b>
	Regulatory History of Opana ER	<b>Ellen Fields, MD, MPH</b> Deputy Director Division of Anesthesia, Analgesia and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
	In Vitro Abuse Deterrent Studies of Opana ER	<b>Erika E. Englund, PhD</b> CMC Reviewer New Drugs Branch II (NDB-II) Division of New Drug API (DNDAPI) Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ), CDER, FDA
	Intranasal Studies for Opana ER and Integration of In Vitro Findings	<b>James M. Tolliver, PhD</b> Pharmacologist Controlled Substance Staff (CSS) CDER, FDA
	Drug Utilization Patterns for Oxymorphone ER and Selected Opioid Analgesics, 2009-2015	<b>Corinne Woods, RPh, MPH</b> Drug Utilization Analyst Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology (OPE) OSE, CDER, FDA
1:55 p.m.	Clarifying Questions	
2:10 p.m.	<b>GUEST SPEAKER PRESENTATION</b>	
	The 2015 Indiana HIV Outbreak: Overview	<b>Jerome Adams, MD, MPH</b> State Health Commissioner Indiana State Department of Health

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

*Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the  
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)*  
March 13-14, 2017

**AGENDA (cont.)**

---

2:30 p.m.	<b>CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) PRESENTATION</b>	
	CDC Outbreak Investigations Involving Opana ER	<b>John T. Brooks, MD</b> Senior Medical Advisor Division of HIV/AIDS Prevention Centers for Disease Control and Prevention (CDC)
2:40 p.m.	<b>FDA PRESENTATIONS (CONT.)</b>	
	Opana ER Adverse Event Reports: Non-Oral Abuse and Thrombotic Microangiopathy	<b>Chaitali Patel, PharmD, BCPS</b> Safety Evaluator Division of Pharmacovigilance II (DPV-II) OPE, OSE, CDER, FDA
	Mechanisms Underlying Thrombotic Microangiopathy Associated with Intravenous Opana ER Abuse	<b>Ryan Hunt, MD</b> ORISE Fellow Division of Plasma Protein Therapeutics (DPPT) Office of Tissues and Advanced Therapies (OTAT) Center for Biologics Evaluation and Research (CBER) FDA
3:05 p.m.	Clarifying Questions	
3:20 p.m.	<b>BREAK</b>	
3:35 p.m.	<b>FDA PRESENTATIONS (CONT.)</b>	
	Statistical Considerations for Evaluating the Abuse-Related Outcomes of Reformulated Opana ER	<b>Diqiong Xie, PhD</b> Mathematical Statistician Division of Biometrics VII (DB-VII) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Review of Postmarketing Epidemiologic Data on Opana ER and Selected Comparators	<b>Jana McAninch, MD, MPH, MS</b> Medical Officer/Epidemiologist DEPI-II, OPE, OSE, CDER, FDA
4:35 p.m.	Clarifying Questions	
5:00 p.m.	<b>ADJOURNMENT</b>	

**FOOD AND DRUG ADMINISTRATION (FDA)**  
Center for Drug Evaluation and Research (CDER)

***Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the  
Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)***

March 13-14, 2017

**AGENDA (cont.)**

---

**Day 2: Tuesday, March 14, 2017**

10:00 a.m.	Call to Order and Introduction of Committee	<b>Almut Winterstein, RPh, PhD, FISPE</b> Chairperson, DSaRM
10:10 a.m.	Conflict of Interest Statement	<b>Stephanie L. Begansky, PharmD</b> Designated Federal Officer, AADPAC
10:15 a.m.	FDA Introductory Remarks	<b>Judy Staffa, PhD, RPh</b> Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
10:30 a.m.	<b>OPEN PUBLIC HEARING</b>	
12:30 p.m.	<b>LUNCH</b>	
1:30 p.m.	Charge to the Committee	<b>Judy Staffa, PhD, RPh</b>
1:35 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	<b>BREAK</b>	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	<b>ADJOURNMENT</b>	