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

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

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DRAFT AGENDA (cont.)

11:00 a.m.	**BREAK**	
11:15 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**FDA PRESENTATIONS**	
	Overview	**Judy Staffa, PhD, RPh**
	Regulatory History: Opana ER	**Ellen Fields, MD, MPH** 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	**Erika E. Englund, PhD** 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	**James M. Tolliver, PhD** Pharmacologist Controlled Substance Staff (CSS) CDER, FDA
	Drug Utilization Patterns for Oxymorphone ER and Select Opioid Analgesics, 2009-2015	**Corinne Woods, RPh, MPH** 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.	**CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) PRESENTATION**	
	CDC Outbreak Investigations Involving Opana ER	**John T. Brooks, MD** Senior Medical Advisor Division of HIV/AIDS Prevention Centers for Disease Control and Prevention (CDC)

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DRAFT AGENDA (cont.)

2:30 p.m.	**GUEST SPEAKER PRESENTATION**	
	2015 Indiana HIV Outbreak: Overview	**Jerome M. Adams, MD, MPH** State Health Commissioner Indiana State Department of Health
2:40 p.m.	**FDA PRESENTATIONS (CONT.)**	
	Opana ER Adverse Event Reports: Non-Oral Abuse and Thrombotic Microangiopathy	**Chaitali Patel, PharmD, BCPS** Safety Evaluator Division of Pharmacovigilance II (DPV-II) OPE, OSE, CDER, FDA
	Mechanisms Underlying Thrombotic Microangiopathy Associated with Intravenous Opana ER Abuse	**Ryan Hunt, MD** 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.	**BREAK**	
3:35 p.m.	**FDA PRESENTATIONS (CONT.)**	
	Statistical Considerations for Evaluating Abuse-Related Outcomes of Reformulated Opana ER	**Diqiong Xie, PhD** 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	**Jana McAninch, MD, MPH, MS** Medical Officer/Epidemiologist DEPI-II, OPE, OSE, CDER, FDA
4:35 p.m.	Clarifying Questions	
5:00 p.m.	**ADJOURNMENT**	

Day 2: Tuesday, March 14, 2017

8:00 a.m.	Call to Order and Introduction of Committee	**Almut Winterstein, MD** Chairperson, DSaRM

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DRAFT AGENDA (cont.)

8:10 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
8:15 a.m.	FDA Introductory Remarks	**Judy Staffa, PhD, RPh** Associate Director for Public Health Initiatives Office of Surveillance and Epidemiology (OSE) CDER, FDA
8: 30 a.m.	**OPEN PUBLIC HEARING**	
10:30 a.m.	**BREAK**	
10:45 a.m.	Charge to the Committee	**Judy Staffa, PhD, RPh**
10:50 a.m.	Questions to the Committee/Committee Discussion	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Questions to the Committee/Committee Discussion (cont.)	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	