

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

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

Tommy Douglas Conference Center
10000 New Hampshire Avenue, Silver Spring, Maryland
April 5, 2017

AGENDA

The committees will be asked to discuss new drug application (NDA) 209777 for oxycodone hydrochloride immediate-release oral tablets, submitted by Inspirion Delivery Sciences, LLC, with the proposed indication of management of moderate to severe pain where the use of an opioid analgesic is appropriate. The product has been formulated with properties intended to deter abuse, and the applicant has submitted data to support these abuse-deterrent properties for this product. The committees will be asked to discuss the overall risk-benefit profile of the product and whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling.

9:15 a.m.	Call to Order and Introduction of Committee	Raeferd E. Brown, Jr., MD, FAAP Chairperson, AADPAC
9:20 a.m.	Conflict of Interest Statement	Stephanie L. Begansky, PharmD Designated Federal Officer, AADPAC
9:25 a.m.	FDA Introductory Remarks	Sharon Hertz, MD Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	APPLICANT PRESENTATIONS	Inspirion Delivery Sciences, LLC
	Introduction	Stefan Aigner, MD Co-founder/Chief Executive Officer Inspirion Delivery Sciences, LLC
	Public Health Need for Abuse-deterrent Immediate-Release Opioid Analgesics	Richard C. Dart, MD, PhD Director, Rocky Mountain Poison and Drug Center Professor of Emergency Medicine University of Colorado School of Medicine Executive Director, RADARS System
	In vitro Physical Manipulation and Chemical Extraction Studies	Robert Bianchi President and Chief of Scientific and Technical Affairs Prescription Drug Research Center

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Intranasal Human Abuse Potential Study **Lynn Webster, MD**
Vice President, Scientific Affairs
PRA Health Sciences

Clinical Perspective **Jeffrey Gudin, MD**
Director, Pain Management and Palliative Care
Englewood Hospital and Medical Center

10:30 a.m. Clarifying Questions

11:00 a.m. **BREAK**

11:15 a.m. **FDA PRESENTATION**

Drug Utilization Patterns for
Oxycodone-Containing Analgesics,
2009-2016 **Tracy Minh Pham, PharmD**
Drug Utilization Data Analyst
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

11:30 a.m. Clarifying Questions

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

1:00 p.m. Open Public Hearing

2:00 p.m. Charge to the Committee **Sharon Hertz, MD**

2:05 p.m. Questions to the Committee/
Committee Discussion

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/
Committee Discussion (cont.)

5:00 p.m. **ADJOURNMENT**