

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)***

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

10903 New Hampshire Avenue, Silver Spring, Maryland

July 26, 2017

AGENDA

The committees will discuss new drug application (NDA) 209653, for oxycodone hydrochloride extended-release oral tablets, submitted by Intellipharmaceuticals Corp., with the proposed indication of management of moderate-to-severe pain when a continuous around the clock analgesic is needed for an extended period of time. 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	Moon Hee V. Choi, PharmD Acting 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	Intellipharmaceuticals Corporation
	Introduction	Isa Odidi, PhD Chairman, CEO, co-CSO, and co-Founder Intellipharmaceuticals Corp.
	Need for Abuse-Deterrent Opioid Analgesics	Richard Dart, MD, PhD Director, Rocky Mountain Poison and Drug Center Professor, University of Colorado Executive Director of the RADARS® System
	Clinical Pharmacology	Beatrice Setnik, PhD Vice President for Scientific & Medical Affairs INC Research, LLC. Adjunct Professor Department of Pharmacology and Toxicology University of Toronto

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APPLICANT PRESENTATIONS (CONT.)

Category 1 Abuse-Deterrent Studies **Edward Cone, PhD**
Principal Scientist
PinneyAssociates
Bethesda, MD
Adjunct Professor of Psychiatry and Behavioral
Sciences (PT)
Johns Hopkins Medicine
Baltimore, MD

Public Health Perspective **Edward Sellers, MD, PhD, FRCPC, FACP**
President and Principal, DL Global Partners Inc.
Professor Emeritus, Pharmacology, Medicine &
Psychiatry
University of Toronto

10:30 a.m. Clarifying Questions

10:45 a.m. **BREAK**

11:00 a.m. **FDA PRESENTATIONS**

Need for Human Abuse Potential **James Tolliver, PhD**
Studies for Evaluation of NDA 209-653 Pharmacologist
Controlled Substance Staff
Office of the Center Director, CDER, FDA

Utilization Trends of Oxycodone ER **Jennie Wong, PharmD**
and Other Extended-Release/Long- Drug Utilization Analyst
Acting Opioid Analgesics, 2012-2016 Division of Epidemiology II
Office of Pharmacovigilance and Epidemiology
Office of Surveillance and Epidemiology
CDER, FDA

Excipients in Oral Opioid Analgesics **Ellen Fields, MD, MPH**
and IV Abuse – A Regulatory Deputy Director
Perspective DAAAP, ODE II, OND, CDER, FDA

11:45 a.m. Clarifying Questions

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12:00 p.m. **GUEST SPEAKER PRESENTATION**

Excipient Harms and Tampering of
Opioid Analgesics

Nabarun Dasgupta, MPH, PhD
Epidemiologist
Injury Prevention Research Center
Department of Epidemiology
Eshelman School of Pharmacy
University of North Carolina
Chapel Hill, NC

12:30 p.m. Clarifying Questions

1:00 p.m. **LUNCH**

2:00 p.m. Open Public Hearing

3:00 p.m. Charge to the Committee

Sharon Hertz, MD

3:05 p.m. Questions to the Committee/
Committee Discussion

3:30 p.m. **BREAK**

3:45 p.m. Questions to the Committee/
Committee Discussion (cont.)

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