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

DRAFT AGENDA

The committees will discuss new drug application (NDA) 209653, for oxycodone hydrochloride extended-release oral tablets, submitted by Intellipharmaceutics 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	**Raeford 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**	**Intellipharmaceutics Corporation**
	Introduction	**Isa Odidi, PhD** Chairman, CEO, co-CSO, and co-Founder Intellipharmaceutics 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

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)
July 26, 2017

DRAFT AGENDA

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 Studies for Evaluation of NDA 209-653	**James Tolliver, PhD** Pharmacologist Controlled Substance Staff Office of the Center Director, CDER, FDA
	Utilization Trends of Oxycodone ER and Other Extended-Release/Long-Acting Opioid Analgesics, 2012-2016	**Jennie Wong, PharmD** Research Officer Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
	Excipients in Oral Opioid Analgesics and IV Abuse – A Regulatory Perspective	**Ellen Fields, MD, MPH** Deputy Director DAAAP, ODE-II, OND, CDER, FDA
11:45 p.m.	Clarifying Questions	

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)
July 26, 2017

DRAFT AGENDA

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**	