**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
January 15, 2020 (**PM Session**)

# DRAFT AGENDA

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*The committees will discuss new drug application (NDA) 209653, for an extended-release oral tablet formulation of oxycodone, submitted by Intellipharmaceutics Corp., for the management of moderate-to-severe pain when a continuous, around-the-clock, opioid 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 whether the applicant has demonstrated abuse-deterrent properties for their product that would support labeling, as well as to discuss the overall risk-benefit profile of the product.*

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| 1:30 p.m. | Call to Order and Introduction of Committee | **Ronald S. Litman, DO, ML**<br>Chairperson, AADPAC |
| 1:35 p.m. | Conflict of Interest Statement | **Moon Hee V. Choi, PharmD**<br>Designated Federal Officer, AADPAC |
| 1:40 p.m. | FDA Opening Remarks | **Rigoberto A. Roca, MD**<br>Director (Acting)<br>Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP)<br>Office of Neuroscience (ON)<br>Office of New Drugs (OND), CDER, FDA |
| 1:45 p.m. | **APPLICANT PRESENTATIONS** | **Intellipharmaceutics Corp.** |
| | Introduction | **Isa Odidi, MBA, PhD, DSc.**<br>Chairman, CEO, co-CSO, co-Founder<br>Intellipharmaceutics Corp. |
| | Abuse-Deterrence (Category 1) Studies and Nonclinical Excipient Safety Studies | **Olu Aloba, RPh, PhD, RAC**<br>Senior Director, CMC Services<br>Camargo Pharmaceutical Services |
| | Clinical Pharmacology and Abuse-Deterrence (Human Abuse Potential) Studies | **Ruth Stevens, PhD, MBA**<br>Chief Scientific Officer, Exec VP<br>Camargo Pharmaceutical Services |
| | Risk/Benefit Profile and Risk Mitigation Plans | **Isa Odidi, MBA, PhD, DSc.** |
| 2:30 p.m. | Clarifying Questions | |

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**DRAFT AGENDA (cont.)**

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| 2:45 p.m. | **FDA PRESENTATIONS** | |
| | Use, Misuse, Abuse and Deaths involving Oxycodone and Other Opioids in the United States | **Matthew Daubresse, MHS, DrPH (candidate)**<br>Epidemiologist, Drug Abuse<br>Division of Epidemiology II<br>Office of Pharmacovigilance and Epidemiology<br>Office of Surveillance and Epidemiology<br>CDER, FDA |
| | Nonclinical Safety Assessment of Aximris XR Excipients | **Jaime D'Agostino, PhD**<br>Nonclinical Reviewer<br>DAAP, ON, OND, CDER, FDA |
| | Agency Interpretation of In Vitro and Human Abuse Potential Studies | **James Tolliver, PhD**<br>Pharmacologist<br>Controlled Substance Staff<br>Office of the Center Director, CDER, FDA |
| | Clinical Summary – Aximris XR | **Elizabeth Kilgore, MD, MS**<br>Medical Officer<br>DAAP, ON, OND, CDER, FDA |
| 3:30 p.m. | Clarifying Questions | |
| 3:45 p.m. | **OPEN PUBLIC HEARING** | |
| 4:15 p.m. | **BREAK** | |
| 4:30 p.m. | Charge to the Committee | **Rigoberto Roca, MD** |
| 4:35 p.m. | Questions to the Committee/ Committee Discussion | |
| 5:30 p.m. | **ADJOURNMENT** | |