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

AGENDA

During the morning session, the committees will discuss new drug application (NDA) 213426, for tramadol 44 milligrams (mg) and celecoxib 56 mg tablet, which contains a fixed-dose combination of an opioid and a non-steroid anti-inflammatory drug, submitted by Esteve Pharmaceuticals, S.A., for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The committees will be asked to discuss the safety and efficacy data as well as the overall risk-benefit profile of the product.

8:00 a.m.	Call to Order and Introduction of Committee	**Ronald S. Litman, DO, ML** Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	FDA Opening Remarks	**Naomi Lowy, MD** Deputy Director (Acting) Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs, CDER, FDA
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Esteve Pharmaceuticals S.A.**
	Introduction	**Mark Mayhew, PhD** Director, CTC Program Esteve Pharmaceuticals, S.A.
	Urgent Need in Opioid Analgesia	**Eugene R. Viscusi, MD** Professor of Anesthesiology Chief of Pain Medicine Director, Acute Pain Management Thomas Jefferson University Philadelphia, PA
	Phase I Clinical Pharmacology Phase 2 Dose-Finding Study	**Carlos R. Plata-Salaman, DSc, MD** Chief Scientific Officer and Chief Medical Officer Esteve Pharmaceuticals, S.A.

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Phase 3 Efficacy and Safety	**Neus Gascon, MD** Head of Medical Sciences Esteve Pharmaceuticals, S.A.
	Benefit-Risk Assessment	**Oscar de Leon-Casasola, MD** Chief, Division of Pain Medicine Professor of Oncology Roswell Park Cancer Institute Professor of Anesthesiology and Medicine The Jacobs School of Medicine at The University of Buffalo
9:15 a.m.	Clarifying Questions	
9:30 a.m.	**FDA PRESENTATION**	
	Review of Recent Data on Use, Misuse, Abuse, and Overdose of Tramadol and Comparator Opioid Analgesics	**Saranrat Wittayanukorn, PhD** Epidemiologist Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
10:00 a.m.	Clarifying Questions	
10:15 a.m.	**BREAK**	
10:30 a.m.	**OPEN PUBLIC HEARING**	
11:00 a.m.	Charge to the Committee	**Naomi Lowy, MD**
11:15 a.m.	Questions to the Committee/ Committee Discussion	
12:30 p.m.	**LUNCH**	

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AGENDA (cont.)

During the afternoon session, the committees will discuss NDA 209653, for an extended-release oral tablet formulation of oxycodone, submitted by Intellipharmaceutics Corp., with 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.

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

AGENDA (cont.)

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)** Epidemiologist, Drug Abuse Division of Epidemiology II Office of Pharmacovigilance and Epidemiology OSE, CDER, FDA
	Nonclinical Safety Assessment of Aximris XR Excipients	**Jaime D'Agostino, PhD** Pharmacology/Toxicology Reviewer Division of Pharmacology/Toxicology for Neuroscience ON, OND, CDER, FDA
	Agency Interpretation of In Vitro and Human Abuse Potential Studies	**James Tolliver, PhD** Pharmacologist Controlled Substance Staff Office of the Center Director, CDER, FDA
	Clinical Summary – Aximris XR	**Elizabeth Kilgore, MD, MS** Medical Officer 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**	