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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
April 19, 2023

AGENDA

The committee will discuss postmarketing requirement (PMR) 3033-11, issued to application holders of new drug applications (NDAs) for extended-release and long-acting opioid analgesics to evaluate long-term efficacy of opioid analgesics and the risk of opioid-induced hyperalgesia. The discussion will focus on a clinical trial designed to address these objectives.

9:00 a.m.	Call to Order and Introduction of Committee	**Brian T. Bateman, MD, MSc** Chairperson, AADPAC
9:10 a.m.	Conflict of Interest Statement	**Rhea Bhatt, MS** Acting Designated Federal Officer
9:15 a.m.	FDA Opening Remarks	**Rigoberto Roca, MD** Director Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	**OPIOID PMR CONSORTIUM (OPC) PRESENTATIONS**	
	Introduction	**Charles E. Argoff, MD** Professor of Neurology, Director Comprehensive Pain Program Albany Medical Center
	Overview of Study Design –3033-11	**Charles E. Argoff, MD**
	Rationale for Study Design –3033-11	**Nathaniel Katz, MD** President Ein Sof Innovation
	Overview of OIH and Its Evaluation	**Martin Angst, MD** Professor, Anesthesiology, Perioperative and Pain Medicine, Vice Chair Strategy and Initiatives Stanford University Medical School
	Protocol Considerations	**Sandra Comer, PhD** Professor of Neurobiology (in Psychiatry) Columbia University
	Conclusions	**Charles E. Argoff, MD**

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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
April 19, 2023

AGENDA (cont.)

11:00 a.m.	Clarifying Questions for OPC	
11:20 a.m.	**BREAK**	
11:30 a.m.	**SPEAKER PRESENTATION**	
	Enriched Enrollment Randomized Withdrawal Design for Studies in Chronic Pain	**John T. Farrar, MD, PhD** Professor of Epidemiology, Anesthesiology, and Critical Care Hospital of the University of Pennsylvania
11:50 a.m.	Clarifying questions for Dr. Farrar	
12:00 p.m.	**LUNCH**	
1:00 p.m.	**FDA PRESENTATION**	
	FDA's Perspective on the Proposed Protocol Intended to Fulfill Postmarketing Requirement (PMR) 3033-11	**Elizabeth Kilgore, MD** Medical Officer DAAP, ON, OND, CDER, FDA
1:20 p.m.	Clarifying questions for FDA	
1:30 p.m.	**OPEN PUBLIC HEARING**	
2:30 p.m.	Charge to the Committee	**Rigoberto Roca, MD**
2:40 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**BREAK**	
4:10 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	