

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

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

DRAFT 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

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DRAFT 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	