

**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 14, 2020

DRAFT AGENDA

The committees will discuss new drug application 211802 for oxycodogol, a new molecular entity full mu-opioid receptor agonist, submitted by Nektar Therapeutics, for the management of chronic low back pain in adult patients with pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options 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	Kalyani Bhatt, Bs, MS Acting Designated Federal Officer, AADPAC
8:10 a.m.	FDA Introductory Remarks	Rigoberto A. Roca, MD Acting Director Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	Nektar Therapeutics
	Introduction	Steve Doberstein, PhD Chief Scientist Nektar Therapeutics
	What We Know About the Use of Opioids in Chronic Pain	Nathaniel Katz, MD, MS Chief Science Officer, WCG—Analgesic Solutions Associate Adjunct Professor of Anesthesia Tufts University School of Medicine
	NKTR-181 Chemistry and Clinical Pharmacology	Jonathan Zalevsky, PhD Chief Research and Development Officer Nektar Therapeutics
	Efficacy and Safety	Margit Tagliaferri, MD Vice President, Clinical Development Nektar Therapeutics
	Abuse Potential	Jonathan Zalevsky, PhD

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DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Perspective

Jeffrey Gudin, MD

Clinical Associate Professor
Department of Anesthesiology and Perioperative
Medicine
Rutgers New Jersey Medical School

Conclusion

Steve Doberstein, PhD

9:45 a.m. Clarifying Questions

9:55 a.m. **BREAK**

10:05 a.m. **GUEST SPEAKER PRESENTATION**

A 12 Month Assessment of Continued
Opioid Efficacy and Safety in Chronic
Non-cancer Pain Patients

John T. Farrar, MD, PhD

Associate Professor of Epidemiology, Neurology, and
Anesthesia
Center for Clinical Epidemiology and Biostatistics
University of Pennsylvania

10:50 a.m. Clarifying Questions

11:00 a.m. **FDA PRESENTATIONS**

Regulatory and Clinical Context for the
Evaluation of Oxycodone

Joshua Lloyd, MD

Clinical Team Leader
DAAP, ON, OND, CDER, FDA

Drug Use and Abuse of ER/LA Opioids

Cynthia Kornegay, PhD

Senior Epidemiologist
Prescription Drug Abuse Team
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology (OPE)
Office of Surveillance and Epidemiology (OSE)

Abuse Potential of Oxycodone

James Tolliver, PhD

Pharmacologist
Controlled Substance Staff
Office of the Center Director, CDER, FDA

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DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Clinical Efficacy and Safety Data
Supporting Oxycodone and Benefit-Risk
Evaluation

Jennifer Nadel, MD
Medical Officer
DAAP, ON, OND, CDER, FDA

12:20 p.m. Clarifying Questions

12:30 p.m. **LUNCH**

1:30 p.m. Open Public Hearing

2:30 p.m. Charge to the Committee

Rigoberto A. Roca, MD

2:45 p.m. Questions to the Committee/Committee
Discussion

3:45 p.m. **BREAK**

3:55 p.m. Questions to the Committee/Committee
Discussion

5:30 p.m. **ADJOURNMENT**