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

AGENDA

The committees will discuss new drug application 211802 for oxycodegol, 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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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	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Regulatory and Clinical Context for the Evaluation of Oxycodegol	**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 Oxycodegol	**James Tolliver, PhD** Pharmacologist Controlled Substance Staff (CSS) Office of the Center Director (OCD), CDER, FDA **Shalini Bansil, MD** Medical Officer CSS, OCD, CDER, FDA
	Clinical Efficacy and Safety Data Supporting Oxycodegol and Benefit-Risk Evaluation	**Jennifer Nadel, MD** Medical Officer DAAP, ON, OND, CDER, FDA
11:35 a.m.	Clarifying Questions	

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11:50 a.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Rigoberto A. Roca, MD**
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:30 p.m.	**ADJOURNMENT**	