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)
DoubleTree by Hilton Hotel Bethesda – Washington DC, Grand Ballroom
8120 Wisconsin Avenue, Bethesda, Maryland
June 26, 2018

AGENDA

The committees will discuss new drug application 022324, oxycodone extended-release capsules, submitted by Pain Therapeutics, with the proposed indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is intended to have abuse-deterrent properties based on its physicochemical properties. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

9:30 a.m.	Call to Order and Introduction of Committee	**Mary Ellen McCann, MD, MPH** Acting Chairperson, AADPAC
9:35 a.m.	Conflict of Interest Statement	**Yinghua Wang, PharmD** Acting Designated Federal Officer, AADPAC
9:40 a.m.	FDA Introductory Remarks	**Sharon Hertz, MD** Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	**APPLICANT PRESENTATIONS**	**Pain Therapeutics, Inc.**
	Introduction	**Remi Barbier** Founder and CEO Pain Therapeutics, Inc.
	In Vitro Abuse Deterrence	**Michael Crowley, PhD** Acting Vice President, Drug Delivery Technologies Pain Therapeutics, Inc.
	In Vivo Abuse Deterrence	**Lynn Webster, MD** Vice President of Scientific Affairs, Neurosciences PRA Health Sciences
	Clinical Development	**Nadav Friedmann, PhD, MD** Chief Operating and Medical Officer Pain Therapeutics, Inc.
	Excipient Safety	**Stephen Montgomery, PhD** Regulatory and Toxicology Consultants, LLC

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Risk Mitigation and Conclusion	**Michael Marsman, PharmD** Senior Vice President, Regulatory Affairs Pain Therapeutics, Inc.
10:45 a.m.	Clarifying Questions	
11:00 a.m.	**BREAK**	
11:15 a.m.	**FDA PRESENTATIONS**	
	Category 3 Oral Study and Category 1 Smoking Study	**James Tolliver, PhD** Pharmacologist Controlled Substance Staff (CSS), CDER, FDA
	Review of Recent Epidemiologic Data on Use, Misuse and Abuse of Oxycodone	**Mallika Mundkur, MD, MPH** Medical Officer Division of Pharmacovigilance II (DPV-II) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Remoxy ER: Multidisciplinary Review	**Lisa Wiltrout, MD** Medical Officer DAAAP, ODE-II, CDER, FDA
12:15 p.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Charge to the Committee	**Sharon Hertz, MD**
2:35 p.m.	Questions to the Committee/Committee Discussion	
3:30 p.m.	**BREAK**	
3:45 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	