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
June 8, 2016

AGENDA

The committees will be asked to discuss new drug application (NDA) 207621, Oxycodone Hydrochloride and Naltrexone Hydrochloride Extended-Release Capsules, submitted by Pfizer, Inc., with the proposed indication of 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 an extended-release formulation intended to have abuse-deterrent properties based on the presence of naltrexone, an opioid antagonist, in the formulation. 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	**Raeford E. Brown, Jr., MD, FAAP** Acting Chairperson, AADPAC
9:35 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
9:40 a.m.	FDA Introductory Remarks	**Ellen Fields, MD, MPH** Deputy Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
	Corrections to FDA In Vitro Abuse Deterrent Open Session Backgrounder	**Benjamin D. Stevens, PhD, MPH** CMC Drug Substance Reviewer Division of New Drug API, Branch II Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ), CDER, FDA
9:45 a.m.	**APPLICANT PRESENTATIONS**	**Pfizer, Inc.**
	ALO-02 Abuse Deterrence Program Introduction	**Sean Donevan, PhD** Medical Affairs Lead Pfizer, Inc.
	ALO-02 Clinical Pharmacology	**Bimal Malhotra, PhD** Clinical Pharmacology Lead Pfizer, Inc.
	ALO-02 Efficacy and Safety	**Gernot Wolfram, MD** Global Clinical Lead Pfizer, Inc.

AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	ALO-02 Abuse Deterrence Program In Vitro	**Sean Donevan, PhD**
	ALO-02 Abuse Deterrence Program Human PK/PD	**Carl Roland, PharmD, MS** Clinical Development & Outcomes and Evidence Pfizer, Inc.
	Conclusions	**Sean Donevan, PhD**
10:45 a.m.	Clarifying Questions	
11:00 a.m.	**BREAK**	
11:15 a.m.	**FDA PRESENTATIONS**	
	Drug Utilization Patterns for Oxycodone ER and Other ER/LA Opioid Analgesics 2011-2015	**Joann H. Lee, PharmD** Drug Utilization Data Analyst Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Troxyca ER (oxycodone HCL and naltrexone HCL) Extended-Release Capsules for Oral Use Labeling Section 9: Drug Abuse	**Elizabeth Kilgore, MD** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Sharon Hertz, MD** Director DAAAP, ODE-II, OND, CDER, FDA
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	

AGENDA (cont.)

3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)
4:00 p.m.	**ADJOURNMENT**