

**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

**DRAFT AGENDA**

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*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.*

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9:30 a.m.	Call to Order and Introduction of Committee	<b>Raeferd E. Brown, Jr., MD, FAAP</b> Acting Chairperson, AADPAC
9:35 a.m.	Conflict of Interest Statement	<b>Stephanie L. Begansky, PharmD</b> Designated Federal Officer, AADPAC
9:40 a.m.	FDA Introductory Remarks	<b>Ellen Fields, MD, MPH</b> Deputy 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.	<b>APPLICANT PRESENTATIONS</b>	<b>Pfizer, Inc.</b>
	ALO-02 Abuse Deterrence Program Introduction	<b>Sean Donevan, PhD</b> Medical Affairs Lead Pfizer Inc.
	ALO-02 Clinical Pharmacology	<b>Bimal Malhotra, PhD</b> Clinical Pharmacology Lead Pfizer Inc.
	ALO-02 Efficacy and Safety	<b>Gernot Wolfram, MD</b> Global Clinical Lead Pfizer Inc.
	ALO-02 Abuse Deterrence Program In Vitro	<b>Sean Donevan, PhD</b>

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**DRAFT AGENDA (cont.)**

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**APPLICANT PRESENTATIONS (CONT.)**

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**  
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 p.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**

3:15 p.m.

Questions to the Committee/Committee Discussion (cont.)

4:00 p.m.

**ADJOURNMENT**