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.
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)  
June 8, 2016  

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**
Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) and the Drug Safety and Risk Management Advisory Committee (DSaRM)  
June 8, 2016

AGENDA (cont.)

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