

**FOOD AND DRUG ADMINISTRATION**  
Center for Drug Evaluation and Research  
*Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and  
Drug Safety & Risk Management Advisory Committee*  
**DRAFT AGENDA**  
**May 5, 2008**

---

*The committees will discuss new drug application (NDA) 22-272, OXYCONTIN® (oxycodone hydrochloride controlled-release) Tablets, Purdue Pharma, L.P., and its safety for the proposed indication of management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time. The sustained-release characteristics of this formulation are purportedly less easily defeated than other formulations of OXYCONTIN.*

---

- |            |  |  |
|------------|--|--|
| 9:15 a.m.  | Call to Order<br>Introduction of Committee                   | <b>John T. Farrar, M.D.</b><br>Acting Chair, ALSDAC  |
|            | Conflict of Interest Statement                               | <b>Teresa Watkins, Pharm.D., R.Ph.</b><br>Acting Designated Federal Officer, ALSDAC/DSaRM  |
| 9:25 a.m.  | Opening Remarks  | <b>Bob A. Rappaport, M.D.</b><br>Director, Division of Anesthesia, Analgesia, &<br>Rheumatology Products CDER/FDA  |
| 9:30 a.m.  | Sponsor Presentations  | <b>J. David Haddox, D.D.S., M.D.</b><br>Vice President,<br>Risk Management and Health Policy<br>Purdue Pharma, L.P.<br><br><b>Jack E. Henningfield, Ph.D.</b><br>Vice President,<br>Research and Health Policy<br>Pinney Associates<br><br><b>Richard Mannion, BPharm., Ph.D.</b><br>Senior Director, Pharmaceuticals<br>Purdue Pharma, L.P. |
| 10:15 a.m. | History of Oxycontin Labeling and Risk<br>Management Program | <b>Mwango Kashoki, M.D.</b><br>Lead Medical Officer,<br>Division of Anesthesia, Analgesia, &<br>Rheumatology Products CDER/FDA   |
| 10:30 a.m. | Utilization Trends   | <b>Kendra Worthy, PharmD</b><br>Drug Utilization Analyst,<br>Office of Surveillance and Epidemiology (OSE)   |
| 10:45 a.m. | Break  |  |

11:00	Prevalence and Patterns of Nonmedical Use of Oxycontin and Other Pain Relievers	<b>Joe Gfroerer</b> Director, Division of Population Surveys Office of Applied Studies, SAMHSA
	Misuse/Abuse of Opioid Analgesics: Findings from The Drug Abuse Warning Network (DAWN)	<b>Judy K. Ball, Ph.D., M.P.A.</b> Acting Director, Division of Operations Office of Applied Studies, SAMHSA
	Admissions to Substance Abuse Treatment for the Abuse of Opioid Analgesics: Findings from the Treatment Episode Data Set (TEDS)	<b>Deborah Trunzo</b> Team Leader, Drug and Alcohol Services Information System (DASIS) Office of Applied Sciences, SAMHSA
12:00 p.m.	Questions for the SAMSHA presenters	
12:15 p.m.	Summary of Drug Abuse Rates in the US	<b>Cathy Dormitzer, Ph.D.</b> Division of Epidemiology Office of Surveillance and Epidemiology (OSE)
	Overview of Reports of Manipulation of OxyContin Tablets	<b>Kristina C. Arnwine, PharmD</b> Acting Team Leader Division of Medication Error Prevention Office of Surveillance and Epidemiology (OSE)
12:30 p.m.	Lunch	
1:30	Open Public Hearing	
2:30 p.m.	Questions to the presenters	
2:45 p.m.	Break	
3:00	Discussion and Questions to the Committee	
4:30 p.m.	Adjourn	