

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*

AGENDA

November 13, 2008

The committees will discuss new drug application 22-324, REMOXY XRT (oxycodone hydrochloride controlled-release) Capsules, Pain Therapeutics Inc., 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 controlled-release characteristics of this formulation are purportedly less easily defeated than other formulations of controlled-release oxycodone.

9:15 a.m.	Call to Order Introduction of Committee	Jeffrey R. Kirsch, M.D. Acting Chair, ALSDAC
	Conflict of Interest Statement	Kalyani Bhatt Designated Federal Officer, ALSDAC
9:25 a.m.	Opening Remarks	Bob A. Rappaport, M.D. Director, Division of Anesthesia, Analgesia, & Rheumatology Products CDER/FDA
9:30 a.m.	History of Oxycontin Labeling and Risk Management Program	Robert Shibuya, M.D. Lead Medical Officer, Division of Anesthesia, Analgesia, & Rheumatology Products, CDER/FDA
9:45 a.m.	Sponsor Presentations	Pain Therapeutics, Inc.
	Introduction	Nadav Friedmann, Ph.D., M.D. Chief Operating and Medical Officer Pain Therapeutics Inc.
	Remoxy In Vitro Testing	Michael Zamloot Senior Vice President, Technical Operations Pain Therapeutics, Inc.
	Remoxy In Vivo Testing	Nadav Friedmann, Ph.D., M.D.
	Remoxy Risk Evaluation & Mitigation Strategy	Eric Carter, Ph.D., M.D. Chief Science Officer, King Pharmaceuticals, Inc.
10:30 a.m.	Remoxy In Vivo Abuse Resistance Studies	Ping Ji, Ph.D. Senior Clinical Pharmacologist Office of Clinical Pharmacology CDER/FDA
10:45 a.m.	Outpatient Drug Utilization Trends for Oxycodone Products	Laura Governale, Pharm.D., M.B.A. Drug Utilization Analyst Team Leader Division of Epidemiology Office of Surveillance and Epidemiology (OSE), CDER/FDA
11:00 a.m.	Break	

11:15 a.m. Prevalence and Patterns of Nonmedical Use of Oxycontin and Other Pain Relievers

Joe Gfroerer
Director, Division of Population Surveys
Office of Applied Studies, SAMHSA

Misuse/Abuse of Opioid Analgesics: Findings from The Drug Abuse Warning Network (DAWN)

CAPT Kathy Poneleit
United States Public Health Service
Director, Division of Facility Surveys
Office of Applied Studies, SAMHSA

Admissions to Substance Abuse Treatment for the Abuse of Opioid Analgesics: Findings from the Treatment Episode Data Set (TEDS)

Deborah Trunzo
Team Leader, Drug and Alcohol Services
Information System (DASIS)
Office of Applied Sciences, SAMHSA

12:15 p.m. Summary of Drug Abuse Rates in the US: Oxycodone

Cathy Dormitzer, Ph.D., M.P.H.
Division of Epidemiology
OSE/CDER/FDA

Overview of Reports of Manipulation of Controlled-release Oxycodone and Controlled-Release Morphine

Richard Abate, R.Ph., M.S.
Safety Evaluator
Division of Medication Error Prevention
OSE/CDER/FDA

12:30 p.m. Lunch

1:30 p.m. Open Public Hearing

2:30 p.m. Break

2:45 p.m. Questions for the Presenters

3:00 p.m. Discussion and Questions to the Committee

4:30 p.m. Adjourn