

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*

TENTATIVE 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	John T. Farrar, M.D. Chair, ALSDAC
	Conflict of Interest Statement	Kalyani Bhatt Designated Federal Officer, ALSDAC/DSaRM
9:25 a.m.	Opening Remarks	
9:30 a.m.	Sponsor Presentations	Pain Therapeutics, Inc.
10:15 a.m.	FDA Presentations	
12:00 noon	Lunch	
1:00	Open Public Hearing	
2:00 p.m.	Questions to the presenters	
3:00	Discussion and Questions to the Committee	
4:30 p.m.	Adjourn	