

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 14, 2008

The committees will discuss new drug application (NDA) 22-321, EMBEDA (morphine sulfate extended-release with sequestered naltrexone hydrochloride) Capsules, Alpharma Pharmaceuticals L.L.C., and its safety for the proposed indication of management of moderate to severe chronic pain. The naltrexone component of this formulation is intended to mitigate abuse of the product when attempts are made to defeat the controlled-release properties of the formulation.

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	Alpharma Pharmaceuticals, LLC
10:15 a.m.	FDA Presentations	
11:00 a.m.	Questions to the Presenters	
12:00 noon	Lunch	
1:00	Open Public Hearing	
2:00 p.m.	Discussion and Questions to the Committee	
4:30 p.m.	Adjourn	