

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 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	Jeffrey R. Kirsch, M.D. Acting Chair, ALSDAC
	Conflict of Interest Statement	Kalyani Bhatt, M.S. 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.	Sponsor Presentations	Alpharma Pharmaceuticals, LLC
	Opening Remarks	Joseph Stauffer, D.O. Chief Medical Officer, Senior Vice President Clinical Research & Medical Affairs Alpharma Pharmaceuticals LLC Assistant Professor Johns Hopkins University, School of Medicine Department of Anesthesiology and Critical Care Division of Pain Medicine
	Defining the Prescription Opioid Abuse Problem	Nathaniel Katz, M.D., M.S. President, Analgesic Research Adjunct Assistant Professor, Tufts University School of Medicine and Public Health
	Formulation Development Program	William Vincek, Ph.D. Senior Vice President Research & Development & Regulatory Affairs Alpharma Pharmaceuticals LLC
	Summary of Clinical Data	Donald Manning, M.D., Ph.D. Vice President of Clinical Research and Development Alpharma Pharmaceuticals LLC Clinical Associate Professor Anesthesiology and Pain Management University of Virginia Health System

Sponsor Presentations (continued)

Abuse-Liability Studies

Sandra D. Comer, Ph.D.

Associate Professor of Clinical Neurobiology
Division on Substance Abuse
Department of Psychiatry
Columbia University & the
New York State Psychiatric Institute

Risk Management Program, REMS &
Closing Remarks

Joseph Stauffer, D.O.

Chief Medical Officer, Senior Vice President
Clinical Research & Medical Affairs
Alpharma Pharmaceuticals LLC
Assistant Professor
Johns Hopkins University, School of Medicine
Department of Anesthesiology and Critical Care
Division of Pain Medicine

10:15 a.m. Break

10:30 a.m. FDA Perspective on ALO-01 Studies

Srikanth C. Nallani, Ph.D.

Senior Clinical Pharmacologist
Office of Clinical Pharmacology
CDER/FDA

10:45 a.m. History of Modified-Release Morphine
And Opioid/Antagonist Combinations

Ellen Fields, M.D.

Lead Medical Officer,
Division of Anesthesia, Analgesia, &
Rheumatology Products CDER/FDA

11:05 a.m. Outpatient Drug Utilization Trends
for Morphine Products

Laura Governale, Pharm.D., M.B.A.

Drug Utilization Analyst Team Leader
Division of Epidemiology
Office of Surveillance and Epidemiology
(OSE), CDER/FDA

11:20 a.m. Summary of Drug Abuse Rates in the US:
Morphine

Cathy Dormitzer, Ph.D., M.P.H.

Division of Epidemiology
OSE/CDER/FDA

11:35 a.m. Questions to the presenters

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

2:00 p.m. Break

2:15 p.m. Discussion and Questions to the Committee

4:30 p.m. Adjourn