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

January 30, 2009

The committees will discuss the safety and efficacy of propoxyphene and propoxyphene-combination products for the treatment of mild to moderate acute pain.

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8:00 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
8:10 a.m.	Opening Remarks	**Sharon H. Hertz, M.D.** Deputy Director Division of Anesthesia, Analgesia, & Rheumatology Products, CDER/FDA
8:20 a.m.	Public Citizen Presentations	**Sidney Wolf, M.D.** Director, Public Citizen's Health Research Group **Steven Karch, M.D.** Assistant, Medical Examiner San Francisco (Retired) Fellow, Faculty of Forensic and Legal Medicine Royal College of Physicians (London)
8:50 a.m.	Sponsor Presentations	**Xanodyne Pharmaceuticals** **Qualitest/Vintage Pharmaceuticals** **James B. Jones, M.D., Pharm.D., FACEP** Vice President, Clinical Development & Medical Affairs Xanodyne Pharmaceuticals, Inc. **Jody L. Green, Ph.D.** Denver Health/Rocky Mountain Poison & Drug Center, Associate Research Director Vanderbilt University, Assistant Professor Denver, CO **Lauren Shaiova, M.D.** Chief of Department of Pain Medicine & Palliative Care Metropolitan Hospital Center Division of Health and Hospital Corporation New York, NY

	Sponsor Presentations cont'd	**Gerald M. Sacks, M.D.** Board Certified Anesthesiologist & Pain Management Specialist Director of Pain Management St. John's Health Center Santa Monica, California
10:05 a.m.	Break	
10:15 a.m.	Regulatory History and Clinical Efficacy of Propoxyphene Products	**Jin Chen, M.D.** Medical Officer Division of Anesthesia, Analgesia, & Rheumatology Products, CDER/FDA
10:30 a.m.	Clinical Pharmacology of Propoxyphene	**Sheetal Agarwal, Ph.D.** Clinical Pharmacology Reviewer Office of Clinical Pharmacology CDER/FDA
10:45 a.m.	Non-Clinical Toxicology Findings	**Steve Leshin, Ph.D.** Pharmacology/Toxicology Reviewer Division of Anesthesia, Analgesia, & Rheumatology Products, CDER/FDA
11:00 a.m.	Utilization Trends for Propoxyphene Products	**Hina Mehta, Pharm.D.** Drug Utilization Analyst Office of Surveillance and Epidemiology CDER/FDA
11:15 a.m.	Findings from AERS Analysis and Epidemiological Review of Cardiotoxicities Associated with Propoxyphene	**Joann Lee, Pharm.D.** Division of Pharmacovigillance II Office of Surveillance and Epidemiology CDER/FDA
11:30 a.m.	Misuse/Abuse of Propoxyphene Products: 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
12:00 p.m	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Questions to the presenters	
2:30 p.m.	Discussion and Questions to the Committee	
3:30 p.m.	Adjourn	