

**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**

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*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<br>Introduction of Committee  | <b>John T. Farrar, M.D.</b><br>Chair, ALSDAC                                |
|            | Conflict of Interest Statement  | <b>Kalyani Bhatt</b><br>Designated Federal Officer, ALSDAC/DSaRM            |
| 8:10 a.m.  | Opening Remarks   |   |
| 8:20 a.m.  | Public Citizen Presentation   | Public Citizen  |
| 8:50 a.m.  | Sponsor Presentations   | <b>Xanodyne Pharmaceuticals</b><br><b>Qualitest/Vintage Pharmaceuticals</b> |
| 10:05 a.m. | Break   |   |
| 10:15 a.m. | Regulatory History and Clinical Efficacy<br>of Propoxyphene Products  |   |
| 10:30 a.m. | Clinical Pharmacology<br>of Propoxyphene  |   |
| 10:45 a.m. | Non-Clinical Toxicology Findings  |   |
| 11:00 a.m. | Utilization Trends for Propoxyphene Products  |   |
| 11:15 a.m. | Findings from AERS Analysis and Epidemiological<br>Review of Cardiotoxicities Associated with<br>Propoxyphene |   |
| 11:30 a.m. | Misuse/Abuse of Propoxyphene Products: Findings<br>from The Drug Abuse Warning Network (DAWN)                 |   |

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

DRAFT