

**FOOD AND DRUG ADMINISTRATION**  
Center for Drug Evaluation and Research  
*Anesthetic and Life Support Drugs Advisory Committee*  
**DRAFT AGENDA**  
**May 7, 2008**

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*The committee will discuss new drug application (NDA) 22-244, fospropofol disodium injection (35 mg/mL) (proposed tradename Aquavan), MGI Pharma, Inc., for the proposed indication of sedation in adult patients undergoing diagnostic or therapeutic procedures.*

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8:00 a.m.	Call to Order Introduction of Committee	<b>John T. Farrar, M.D.</b> Acting Chair, ALSDAC
	Conflict of Interest Statement	<b>Teresa Watkins, Pharm.D., R.Ph.</b> Acting Designated Federal Officer, ALSDAC
8:10 a.m.	Opening Remarks	<b>Rigoberto Roca, M.D.</b> Deputy Director, Division of Anesthesia, Analgesia, and Rheumatology Products CDER/FDA
8:15 a.m.	Sponsor Presentations	MGI Pharma, Inc.
	Introduction	<b>Jacqueline M. Kline, Ph.D.</b> Director, Regulatory Affairs MGI Pharma, Inc.
	Medical Need	<b>Lawrence B. Cohen, M.D.</b> Associate Clinical Professor, The Mount Sinai Hospital New York
	Clinical Pharmacology	<b>Stephen Waters, Ph.D.</b> Vice President, Science & Technology MGI Pharma, Inc.
	Efficacy	<b>Jacqueline M. Kline, Ph.D.</b> Director, Regulatory Affairs MGI Pharma, Inc.
	Safety	<b>Michael T. Cullen, M.D.</b> Chief Medical Officer, MGI Pharma, Inc.
	Risk/Benefit Summary	<b>John Leslie, M.D., M.B.A</b> Professor of Anesthesiology, Mayo Clinic College of Medicine
9:45 a.m.	Questions from the committee to MGI	
10:15 a.m.	Break	

10:30 a.m. FDA Presentations

FDA Perspective on the Application

**Lex Schultheis, M.D., Ph.D.**  
Medical Officer, Division of Anesthesia,  
Analgesia, and Rheumatology Products  
CDER/FDA

11:00 a.m. Questions from the committee

12:00 p.m. Lunch Break

1:00 p.m. Open Public Hearing

2:00 p.m. Discussion

3:00 p.m. Break

3:15 p.m. Questions to the committee and Recommendations

4:30 p.m. Adjourn