

**FOOD AND DRUG ADMINISTRATION**  
Center for Drug Evaluation and Research  
Anesthetic and Life Support Drugs Advisory Committee (ALSDAC)  
FDA White Oak Campus, Building 31, the Great Room,  
White Oak Conference Center (Rm. 1503), Silver Spring, MD  
**March 10, 2011**

**DRAFT AGENDA**

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The committee will: (1) receive updates regarding neurodegenerative findings (findings related to degeneration in the nervous system) in juvenile animals exposed to anesthetic drugs, as well as be provided with results from human epidemiological studies using anesthesia in children (information related to studies of patterns and causes of disease); (2) discuss the relevance of these findings to pediatric patients and provide guidance for future preclinical and clinical studies, and (3) discuss the potential implications of these data upon the practice of pediatric anesthesia as well as the communication of the risk of sedative/anesthetic agents to prescribers and parents.

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8:00 a.m.	Call to Order Introduction of Committee	<b>Jeffrey R. Kirsch, M.D.</b> Chair, ALSDAC
8:05 a.m.	Conflict of Interest Statement	<b>Kalyani Bhatt, B.S., M.S.</b> Designated Federal Officer, ALSDAC
8:10 a.m.	Welcome and Introduction	<b>Bob A. Rappaport, M.D.</b> Director, Division of Anesthesia and Analgesia Products (DAAP), CDER/FDA
8:15 a.m.	Anesthetic-Induced Neurodegeneration: Update of Pre-Clinical Data since 2007	<b>R. Daniel Mellon, Ph.D.</b> Supervisor, Pharmacology and Toxicology, DAAP, CDER/FDA
8:50 a.m.	Ketamine Anesthesia and Long-Lasting Cognitive Deficits in Rhesus Monkeys	<b>Merle Paule, Ph.D.</b> Director, Division of Neurotoxicology National Center for Toxicological Research, FDA
9:15 a.m.	Anesthesia-induced Neuroapoptosis and Oligo- apoptosis in the Developing Primate Brain	<b>John Olney, M.D. (Guest Speaker)</b> John P. Feighner Professor of Psychiatry, Professor of Pathology and Immunology, Washington University in St. Louis
9:40 a.m.	Translating Developmental Time from Experimental Species to Humans	<b>Barbara Clancy, Ph.D. (Speaker and Discussant)</b> Associate Professor, Department of Biology University of Central Arkansas
10:05 a.m.	<b>BREAK</b>	
10:20 a.m.	Review of Clinical Data	<b>Arthur Simone, M.D., Ph.D.</b> Medical Officer, DAAP, CDER/FDA
10:40 a.m.	Ketamine and the Neonatal Brain:  Rat Pups vs. Babies	<b>K.J.S. 'Sunny' Anand, MBBS, D.Phil (Guest Speaker)</b> Division Chief of Pediatric Critical Care Medicine University of Tennessee at Memphis
11:05 a.m.	What is our Professional Responsibility?: Focus on Research and Risk Communication	<b>Robert M. 'Skip' Nelson, M.D., Ph.D.</b> Office of Pediatric Therapeutics, Office of the Commissioner, FDA

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- 11:25 a.m. Follow-up Questions to the Presenters
- 12:00 p.m. **LUNCH**
- 1:00 p.m. Open Public Hearing
- 2:00 p.m. Discussion and Questions to the Committee
- 3:00 p.m. **BREAK**
- 3:15 p.m. Discussion and Questions to the Committee (continued)
- 4:30 p.m. Adjourn