

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
Anesthetic and Life Support Drugs Advisory Committee Meeting
Doubletree Hotel and Executive Meeting Center, 1750 Rockville Pike, Rockville, Maryland
March 29, 2007
DRAFT
AGENDA**

The committee will review presentations regarding neurodegenerative findings in juvenile animals exposed to anesthetic drugs (e.g., ketamine), discuss the relevance of these findings to pediatric patient and provide guidance for future preclinical and clinical studies.

8:00 a.m.	Call to Order and Introductions	Steven L. Shafer, M.D. Acting Chair, Anesthetic and Life Support Drugs Advisory Committee
8:10 a.m.	Conflict of Interest Statement	LCDR Cathy Groupe, M.P.H. Designated Federal Official Anesthetic and Life Support Drugs Advisory Committee

PRESENTATIONS:

8:15 a.m.	Introductory Remarks Background	Bob A. Rappaport, M.D. Director, Division of Anesthesia, Analgesia and Rheumatology Products, FDA
8:30 a.m.	Clinical Pediatric Anesthesia Overview	Arthur F. Simone, M.D., Ph.D. Medical Officer, Division of Anesthesia, Analgesia and Rheumatology Products, FDA
8:50 a.m.	History of Preclinical Data Anesthetic-Induced Neuroapoptosis	R. Daniel Mellon, Ph.D. Supervisor, Pharmacology and Toxicology, Division of Anesthesia, Analgesia and Rheumatology Products, FDA
9:10 a.m.	Preclinical Developmental Neurotoxicity	John Olney, M.D. Department of Psychiatry and Neuropathology Washington University School of Medicine
9:40 a.m.	Preclinical Model of Anesthetic-Induced Neurotoxicity	Vesna Jevtovic-Todorovic, M.D., Ph.D. Associate Professor of Anesthesiology and Neuroscience University of Virginia Department of Anesthesiology
10:15 a.m.		Break
10:30 a.m.	Overview of FDA (CDER/NCTR) Studies to Evaluate the Potential For Anesthetic-Induced Neurotoxicity	William Slikker, Jr., Ph.D. Director, Division of Neurotoxicology National Center for Toxicological Research (NCTR), FDA
11:15 a.m.	Clinical Perspective: Implications Of Non-Clinical Findings	Sulpicio de Guzman Soriano III, M.D. Senior Associate, Department of Anesthesia Children's Hospital – Boston, Massachusetts
11:45 a.m.		Clarifying Questions from the Committee
12:00 noon		Lunch

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1:00 p.m.	Open Public Hearing
2:00 p.m.	Break
2:15 p.m.	Committee Discussion and Questions
5:00 p.m.	Adjourn