

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANESTHETIC AND LIFE SUPPORT DRUGS ADVISORY COMMITTEE (ALSDAC)
Holiday Inn, Ballrooms, 2 Montgomery Village Avenue, Gaithersburg, MD
DRAFT AGENDA
January 30, 2002

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| 8:00 a.m. | Call to Order and Introductions | Nathaniel P. Katz, M.D. Acting Chair, ALSAC |
| | Conflict of Interest Statement | Kimberly L. Topper Executive Secretary, ALSDAC |
| 8:20 a.m. | Welcome and Introductory Comments | Cynthia McCormick, M.D. Director, Division of Anesthetic, Critical Care and Addiction Drug Products (DACADP), FDA |
| 8:35 a.m. | Open Public Hearing | |
| 9:50 a.m. | Introduction to Session I: Opiate Analgesic Development and Use | Bob Rappaport, M.D. Deputy Director, DACADP, FDA |
| 10:00 a.m. | Pain Treatment Guidelines | Bruce Allen Levy, M.D., J.D. |
| 10:30 a.m. | Treatment of Patients with Chronic Pain | Russell Portenoy, M.D. Department of Pain Medicine and Palliative Ca Beth Israel Medical Center |
| 11:00 a.m. | Break | |
| 11:15 a.m. | Opiate Analgesic Trials and Drug Development Plans | Gerald DalPan, M.D. Medical Officer, DACADP, FDA |
| 11:30 p.m. | Questions and Discussion | |
| 12:30 p.m. | Lunch | |
| 1:30 p.m. | Introduction to Session II Opiate Analgesic Use in Pediatric Patients | Bob Rappaport, M.D. Deputy Director, DACADP, FDA |
| 1:45 p.m. | Pediatric Analgesic Use | Debra Friedman, M.D. University of Washington, Children's Hospital and Regional Medical Center |
| 2:15 p.m. | Pediatric Exclusivity and the Pediatric Rule | Rosemary Roberts, M.D. Pediatrics Team, FDA |
| 2:40 p.m. | Pediatric Opiate Analgesic Trials and Development Plans: Case Studies | Nancy Chang, M.D. Medical Officer, DACADP, FDA |
| 3:00 p.m. | Questions and Discussion | |
| 5:30 p.m. | Adjourn | |