

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANESTHETIC & LIFE SUPPORT DRUGS ADVISORY
COMMITTEE MEETING
AGENDA

November 18, 2003
Holiday Inn, Gaithersburg, Maryland

8:00 a.m. Call to Order Nathaniel Katz, M.D., M.P.H., Chair, ALSDAC
Terese Horlocker, M.D., Co-Chair

Introduction of Committee

Conflict of Interest Statement Johanna Clifford, M.S., RN, BSN
Executive Secretary, ALSDAC

8:15 a.m. Opening Remarks

8:30 a.m. Inapsine Basis for Approval

**8:45 a.m. Droperidol since 2001:
FDA Risk Assessment**

9:30 a.m. *Break*

**9:45 a.m. Prospective Controlled Study of QTc
Prolongation by Droperidol in Healthy
Volunteers**

**10:15 a.m. QTc Prolongation: Controversies,
Consensus, Case Histories**

11:30 a.m. Droperidol Study Proposals

12:15 p.m. *Lunch*

1:15 p.m. Open Public Hearing

2:15 p.m. *Break*

**2:30 p.m. Charge to the Committee
Questions for Discussion**

4:30 p.m. Adjourn