

Draft Agenda: Monday, November 18, 2002

**Joint Meeting of the Peripheral and Central Nervous System Drugs
Advisory Committee with the Medical Imaging Drugs Advisory
Committee**

Food and Drug Administration
Holiday Inn, Gaithersburg, Maryland

**The Role of Brain Imaging as an Outcome Measure in Phase 3
Drug Trials in Alzheimer's Disease**

- 8:00 Call to Order, Introductions**
Claudia Kawas, M.D., Acting Chair, PCNS
- Conflict of Interest Statement**
Sandra Titus, Ph.D., Executive Secretary, PCNS
- 8:15 FDA Overview of Issues**
Overview of Issues, Russell Katz, M.D., Director, Neuropharmacological Drug Products
- 8:30 Overview of Imaging**
Charles De Carli, MD
- 8:45 Statistical Issues: Imaging as a surrogate Marker**
.TBA
- 9:00 Questions to the two speakers**
- 9:15 Volumetric MRI and Related Subjects**
Clifford Jack, M.D.
Nick Fox, M.D.
H. Cecil Charles, Ph.D.
Michael Grundman, M.D.
- 10:15 Questions to speakers**
- 10:30 Break**
- 11:00 Open Public Hearing**
Eric Reisman, M.D., University of Arizona and Good Samaritan Positron Emission Tomography Center
- 12:00 Lunch Break**
- 1:00 MR Spectroscopy and PET**
Michael Weiner, M.D.
Murali Doraiswamy, MD
William Jaquist, MD
- 1:45 Imaging as a surrogate Marker**
Michael Hughes, Ph.D.
- 2:00 Questions to speakers**
- 2:30 Discussion of questions posed by FDA**
- 3:30 Break**
- 3:45 Continuation of Discussion**
- 5:00 Adjourn**

