

Meeting of the Peripheral and Central Nervous System Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Holiday Inn, Gaithersburg, Maryland

Agenda for November 18, 2002

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

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| 8:00 | Call to Order, Introductions | Claudia Kawas, M.D., Acting Chair, PCNS |
| | Conflict of Interest Statement | Thomas H. Perez., Executive Secretary, PCNS |
| | Welcome and Opening Remarks | Patricia Love, M.D., Director, Medical Imaging and
Radiopharmaceutical Drug Products |
| 8:15 | FDA Overview of Issues | Russell Katz, M.D., Director, Neuropharmacological Drug Products |
| 8:30 | Overview of Imaging | Charles De Carli, M.D. |
| 8:45 | Surrogate Endpoints as Measures of Efficacy:
Complexities and Limitations | Michael Hughes, Ph.D. |
| 9:00 | Questions to presenters | |
| 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 presenters | |
| 10:30 | Break | |
| 10:45 | MR Spectroscopy and PET | Michael Weiner, M.D.
Murali Doraiswamy, M.D.
William Jagust, M.D.
Gary Small, M.D. |
| 11:45 | Questions to presenters | |
| 12:00 | Validating Surrogate Endpoints | Michael Hughes, Ph.D. |
| 12:15 | Questions to presenters | |
| 12:30 | Lunch Break | |
| 1:30 | Open Public Hearing | Eric Reiman, M.D., University of Arizona and Good Samaritan Positron Emission Tomography Center
Mary Pendergast, Elan Pharmaceutical Management Corp. |
| 2:30 | Discussion of Issues Presented by FDA | |
| 3:30 | Break | |
| 3:45 | Continuation of Discussion | |
| 5:00 | Adjourn | |