

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Pediatric Oncology Subcommittee

Of the

Oncologic Drugs Advisory Committee

AGENDA

December 6, 2006

8:30 a.m. Call to Order **Michael Link, M.D.**
Introduction of Committee Acting Chair, Pediatric Oncology Subcommittee

Conflict of Interest Statement **Johanna Clifford, M.Sc., RN**
Executive Secretary, ODAC

The committee will consider endpoints for trials intended to support the approval of new drugs to treat pediatric brain tumors.

8:40 a.m. Opening Remarks **Karen Weiss, M.D., Deputy Director**
Office of Oncology Products (OOP), CDER, FDA

9:00 a.m. Non-Inferiority Trial Design **Rajeshwari Sridhara, Ph.D., Statistical Team Leader**
for Oncology Drugs, Division of Biometrics V,
Office of Biostatistics, CDER, FDA

9:10 a.m. Summary of January 2006 Workshop on **Larry Kun, M.D**
Clinical Trial End Points in Primary Chair, Dept of Radiological Sciences
Brain Tumors St. Jude Children's Research Hospital

9:30 a.m. Biology of Pediatric Brain Tumors and the **Mark Kieran, M.D., Ph.D.**
Heterogeneity of this Disease Dept. of Pediatric Oncology, Dana Farber Cancer Institute
Assistant Professor of Pediatrics, Harvard Medical School

9:50 a.m. Children's Oncology Group Experience **Ian Pollack, M.D. F.A.C.S., F.A.A.P.**
with Pediatric Brain Tumor Clinical Trials Walter Dandy Professor of Neurosurgery
Chief, Pediatric Neurosurgery
Children's Hospital of Pittsburgh
Director, UPCI Brain Tumor Program
University of Pittsburgh School of Medicine

10:10 a.m. Neurocognitive Sequelae of Pediatric **Daniel Armstrong, Ph.D.**
Brain Tumors Professor & Associate Chair, Dept of Pediatrics
Director, Mailman Center for Child Development
Associate Chief of Staff, Holtz Children's Hosp at Univ of
Miami/Jackson Memorial Medical Center

10:30 a.m. Break

10:45 a.m. *Questions to the Presenters*

11:00 a.m. Open Public Hearing

12:00 p.m. Lunch

2:00 p.m. *Questions to the Pediatric Oncology Subcommittee and Discussion*

5:00 p.m. Adjourn