

Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
ACS Building, 5630 Fishers Lane, Rockville, MD

Pediatric Labeling for Oncology Products

Agenda for March 4, 2003

- 8:30 Call to order and Introduction** Victor M. Santana, M.D., Chair
Conflict of Interest Thomas H. Perez, M.P.H., Executive Secretary
Welcome Richard Pazdur, M.D.,
Director, Division of Oncology Drug Products
- 8:45 History of Pediatric Labeling** Steven Hirschfeld, M.D., Ph.D., Medical Officer
Division of Oncology Drug Products
- 9:05 Case Studies of Pediatric Submissions for Oncology Products**
Anne Zajicek, Pharm.D., M.D.
Ramzi Dagher, M.D.
Steven Hirschfeld, M.D., Ph.D.
Susan Honig, M.D.
Alla Shapiro, M.D.
- 9:50 Committee Questions to the Presenters**
- 10:10 Break**
- 10:25 Open Public Hearing** Edward J. Allera, B.S., J.D.,
Buchanan & Ingersoll
- 11:25 Discussion of Questions to the Committee**
- 12:00 Lunch**
- 1:00 Discussion of Questions to the Committee**
- 3:15 Chairman's Summary of Discussion**
- 3:30 Adjourn**