Summary Minutes of the
Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee
April 16, 2008
Location: Food and Drug Administration, Center for Drug Evaluation and Research, Advisory Committee Conference Room, Rm. 1066, 5630 Fishers Lane, Rockville, MD.

All external requests for the meeting transcripts should be submitted to the CDER, Freedom of Information office.

These summary minutes for the April 16, 2008 Meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee of the Food and Drug Administration were approved on - ____5/1/2008_____.

I certify that I attended the April 16, 2008 meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

____/s/_____
Nicole Vesely, Pharm.D.
Designated Federal Official, ODAC

_____/s/_____
Michael Link, M.D.
Acting Subcommittee Chair

Meeting of the Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee
April 16, 2008

The Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research met on April 16, 2008 at the Food and Drug Administration, Center for Drug Evaluation and Research, Advisory Committee Conference Room, Rm. 1066, 5630 Fishers Lane, Rockville, MD. Prior to the meeting, members and invited consultants were provided copies of the background material from the FDA. The meeting was called to order by Michael Link, M.D. (Acting Subcommittee Chair); the conflict of interest statement was read into the record by Nicole Vesely, Pharm.D. (Designated Federal Official). There were approximately 75 persons in attendance. There was one speaker for the Open Public Hearing session.

Issue: The subcommittee will consider and discuss opportunities for enhancing global pediatric oncology drug development and expanding international regulatory interactions given the January 2007 legislation introduced in the European Union that governs the development and authorization of medicines for use in children aged 0 to 17 years.

Attendance:
Oncologic Drug Advisory Committee Members Present:
Michael Link, M.D., Ronald Richardson, M.D.

Special Government Employee Consultants:
Gregory Reaman, M.D., Peter Adamson, M.D., Susan Blaney, M.D., Jerry Finklestein, M.D., C. Patrick Reynolds, M.D., Ph.D., Victor Santana, M.D., Cindy Schwartz, M.D., Malcolm Smith, M.D., Ph.D., Sharon Murphy, M.D., Angela Myers, M.D. (Patient Representative), Melissa Hudson, M.D. (Pediatric Advisory Committee Member), Naomi Winick, M.D., Kenneth Cohen, M.D., Elaine Vining (Consumer Representative-Pediatric Advisory Committee Member)

Guest Speakers
Agnes Saint-Raymond, M.D. (EMEA)
Ralf Herold, M.D. (EMEA)-call in

Industry Representative
Gregory Curt, M.D. (Industry Representative)

FDA Participants:
Richard Pazdur, M.D.
Karen Weiss, M.D.
Dianne Murphy, M.D.
Murray Lumpkin, M.D., M.Sc.

Designated Federal Official:
Nicole Vesely, Pharm.D.

Open Public Hearing Speaker:
Matthew Alsante

The agenda was as follows:

Call to Order and Introductions	**Michael Link, M.D.** Acting Chair Pediatric Oncology Subcommittee

Conflict of Interest Statement	**Nicole Vesely, Pharm.D.** Designated Federal Official Pediatric Oncology Subcommittee

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Opening Remarks	**Karen Weiss, M.D.** Deputy Director, Office of Oncology Drug Products (OODP) Office of New Drugs (OND), FDA
Brief Overview FDAAA	**Lisa Mathis, M.D.** Office of New Drugs Associate Director Pediatric and Maternal Health Staff, Office of New Drugs (OND), FDA

Clarification questions from committee

Introduction to International Cooperation	**Murray Lumpkin, M.D., M.Sc.** Deputy Commissioner International and Special Programs, FDA
European Medicines Directive	**Agnes Saint-Raymond, M.D.** Head of Sector Scientific Advice and Orphan Drugs Paediatric Medicinal Products, EMEA

Clarification questions from committee

Overview FDA and EMEA Interactions	**Dianne Murphy, M.D.** Director, Office of Pediatric Therapeutics (OPT) Office of the Commissioner (OC), FDA
Case Examples	**Jean Temeck, M.D.** Lead Medical Officer Office of Pediatric Therapeutics (OPT), Office of the Commissioner (OC), FDA

Clarification questions from committee

Open Public Hearing

Prioritization of New Agents in Pediatric Oncology: A Perspective From CTEP/NCI	**Malcolm Smith, M.D., Ph.D.** Associate Branch Chief, Pediatrics Cancer Therapy Evaluation Program, NCI
Overview of Pediatric Transatlantic Studies	**Gregory H. Reaman, M.D.** Professor of Pediatrics The George Washington University School of Medicine and Health Sciences

Clarification questions from committee and Discussion

Questions to the Subcommittee:

No questions were posed to the Subcommittee. Please see transcript for detailed discussion.

The session adjourned @ approximately 3:30 p.m.