Food and Drug Administration
Center for Drug Evaluation and Research

SUMMARY MINUTES
PEDIATRIC ADVISORY SUBCOMMITTEE MEETING

A Subcommittee of the Anti-Infective Drugs Advisory Committee
Holiday Inn, Silver Spring, Maryland
April 23, 1999

Pediatric Advisory Subcommittee:
Anti-Infective Members
P. Joan Chesney, MD, Chair
Judith R. O'Fallon, PhD
Keith A. Rodvold, PharmD

SGE Consultants
Kathryn Edwards, MD
Robert Fink, MD
Susan Fuchs, MD
Mark Hudak, MD
Naomi Luban, MD

Guests
David Danford, MD
Richard Gorman, MD, FAAP
Dave Grinder, MS
Michael Horan, MD, ScM
Daniel Notterman, MD, FAAP
Tim Westmoreland, Esq.

FDA Participants:
Leanne Cusumano, Esq.
Murray Lumpkin, MD
Dianne Murphy, MD
Monica Roberts, MD
Rosemary Roberts, MD
Karen Weiss, MD

These summary minutes for the April 23, 1999 Anti-Infective Drugs Advisory Committee meeting were approved on 6/28/99.

I certify that I attended the April 23, 1999 Anti-Infective Drugs Advisory Committee meeting and that these minutes accurately reflect what transpired.

Rhonda W. Stover, RPh
Executive Secretary

P. Joan Chesney, MD
Chair

The April 23, 1999 meeting of the Pediatric Advisory Subcommittee consisted of a one-day open session.

The full transcript of this meeting and available slides are at http://www.fda.gov/ohrms/dockets/ac/cder99t.htm#Anti-InfectiveDrugs.

Additional information on this meeting and the pediatric initiatives are at www.fda.gov/cder/pediatric.

MEETING PROCEEDINGS-OPEN SESSION-April 23, 1999

Background materials provided to committee members included a briefing document from the FDA. Approximately 125 persons were in attendance in the meeting room. Audio, video, and webcasting services were available to a wider audience by private companies not affiliated with the FDA.

Call to Order

P. Joan Chesney, M.D., Chair, called the meeting to order at 8:30 am. The meeting participants at the table introduced themselves.

Conflict of Interest Statement

Rhonda W. Stover, RPh, Executive Secretary, read the conflict of interest statement. No additional waivers other than general matters waivers were needed for this meeting.

Introduction

Murray Lumpkin, MD, Deputy Center Director, Office of Review Management, CDER, FDA, gave the FDA introductory remarks. Dr. Lumpkin reviewed the purpose of the meeting which was to familiarize the subcommittee with its role in the agency's pediatric initiatives and to obtain their questions and comments.

Morning FDA Presentations

Dianne Murphy, MD, Associate Director of Pediatrics, CDER, FDA and Rosemary Roberts, MD, Medical Officer, Pediatrics Team, CDER, FDA, made presentations that addressed the history of the pediatric regulatory initiatives and the interaction between the Food and Drug Administration Modernization Act (FDAMA) and the Pediatric Rule. Karen Weiss, MD, discussed the Lessons Learned from Pediatric Development Programs.

Guest Presentations

Guest presentations were given by Daniel Notterman, MD, FAAP, American Academy of Pediatrics, Michael Horan, MD, ScM, Pharmaceutical Manufacturers of America, Dave Grinder, MS, Pediatric Pharmacy Advocacy Group, and Timothy Westmoreland, Esq., Elizabeth Glaser Pediatric AIDS Foundation.

Open Public Hearing

There were no participants for the open public hearing.

Afternoon FDA Presentations

Leanne Cusumano, Esq., Regulatory Policy Staff, CDER, FDA, reviewed the Priority List. Dr. Rosemary Roberts, MD, addressed the topic of Waivers. Monica Roberts, MD, Division of Anesthetic, Critical Care, and Addiction Drug Products, CDER, FDA, discussed Timing of Initiation of Pediatric Studies.

Questions to the Subcommittee

No formal questions were posed to the subcommittee for discussion or vote. Throughout the meeting, the presenters asked the subcommittee for questions and comments on the pediatric initiatives and associated issues of exclusivity, waivers, and pediatric trial design. The subcommittee provided the agency with input consistent with the meeting purpose.

The meeting was adjourned at 3:15 p.m.