

Pediatric Subcommittee
of the
Anti-Infective Drugs Advisory Committee
Center for Drug Evaluation and Research, Food and Drug Administration
ACS Conference Room, Room 1066, 5630 Fishers Lane, Rockville, MD
April 23, 2001

AGENDA

Issue: Treatment of Chronic Hepatitis C in Children

- 8:00 a.m. Call to Order/Introductions**
P. Joan Chesney, M.D., Chair, Pediatric Advisory Subcommittee
- Conflict of Interest Statement**
Jayne E. Peterson, R.Ph., J.D., Subcommittee Executive Secretary
- 8:05 a.m. Welcome/Introduction to Meeting**
Dianne Murphy, M.D., Associate Director of Pediatrics, Center for Drug Evaluation and Research (CDER), FDA
- 8:15 a.m. Review of Meeting Agenda/Background Information and Overview**
Russell Fleischer, PA-C, MPH, Senior Clinical Analyst, Division of Anti-Viral Drug Products, CDER
- 8:30 a.m. Virology and Immunology of Hepatitis C**
Barbara Rehermann, M.D., Liver Diseases Section, DDB, National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)
- 8:50 a.m. The Natural History of Hepatitis C in the Adult Population**
Leonard Seeff, M.D., NIDDK, NIH
- 9:25 a.m. Hepatitis C in Children**
Maureen Jonas, M.D., Division of Gastroenterology, Children's Hospital, Boston, MA
- 9:45 a.m. Pediatric Drug Development: Overview of FDA Initiatives**
Karen Weiss, M.D., Director, Division of Clinical Trial Design and Analysis (DCTDA), Office of Therapeutics Research and Review (OTRR), Center for Biologics Evaluation and Research (CBER), FDA
- 10:05 a.m. Questions from the Subcommittee**
- 10:15 a.m. Break**

Pediatric Subcommittee
of the
Anti-Infective Drugs Advisory Committee
Center for Drug Evaluation and Research, Food and Drug Administration
ACS Conference Room, Room 1066, 5630 Fishers Lane, Rockville, MD
April 23, 2001

AGENDA (cont.)

Issue: Treatment of Chronic Hepatitis C in Children

- 10:30 a.m. Open Public Hearing**
(*30 minutes allocated unless public participation does not last that long.)
- 11:00 a.m. Subcommittee Discussion of the Issues/Questions**
- 12:00 Lunch**
- 1:00 p.m. Continuation of Subcommittee Discussion of Issues/Questions**
- 3:00 p.m. Break**
- 3:15 p.m. Continuation of Subcommittee Discussion of Issues/Questions**
- 4:30 p.m. Agency Update to the Subcommittee**
Dianne Murphy, M.D.
- 4:45 p.m. Subcommittee Questions to Agency**
- 4:55 p.m. Closing Remarks**
Dianne Murphy, M.D.