

Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
ACS Conference Room, Room 1066, 5630 Fishers Lane, Rockville, MD

Draft Agenda for February 3, 2004

Section 17, Best Pharmaceuticals for Children Act, Adverse Event Reporting

- 9:00 **Call to Order, Introductions:** Joan P. Chesney, M.D., Chair
- Meeting Statement:** Thomas H. Perez, M.P.H.
Executive Secretary
- 9:15 **Adverse Event Reports per Section 17 of BPCA** Solomon Iyasu, M.D.
Lead Medical Officer
Division of Pediatric
Drug Development
- 9:45 **Open Public Hearing**
- 10:15 **Break**

***Use of Imaging Drugs in Conjunction with
Cardiac Imaging Procedures in the Pediatric Population***

- 10:30 **Pediatric Regulatory Update** Dianne Murphy, M.D.
Director, Office of Counter-
terrorism and Pediatric Drug
Development
- 10:45 **FDA Perspective** Sally Loewke, M.D.
Acting Director
Division of Medical Imaging and
Radiologic Drug Products
- 11:05 **AAP Perspective** John Ring, M.D.
University of Tennessee Health
Science Center
- 11:20 **Cardiology Perspective** Tal Geva, M.D.
Boston Children's Hospital
- 11:50 **Q&A for Speakers**
- 12:15 **Lunch**
- 1:15 **Contrast Enhanced Cardiac Magnetic
Resonance Imaging** Mark Fogel, M.D.
The Children's Hospital of
Philadelphia
- 1:45 **Contrast Enhanced Cardiac
Computed Tomography** Marilyn Siegel, M.D.
Washington University School of
Medicine

- 2:15 **Contrast Enhanced Cardiac Ultrasound** Craig Sable, M.D.
University of Maryland School of
Medicine
- 2:45 **Radiopharmaceuticals in Nuclear Cardiac Imaging** Vasken Dilsizian, M.D.
University of Maryland School of
Medicine
- 3:15 **Q&A for speakers**
- 3:45 **Break**
- 4:00 **Open Public Hearing**
- 5:00 **Final Wrap-up and Adjourn**

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Draft Agenda for February 4, 2004

***Use of Imaging Drugs in Conjunction with
Cardiac Imaging Procedures in the Pediatric Population***

- 8:00 **Call to Order, Introductions:** Joan P. Chesney, M.D., Chair
- Meeting Statement:** Thomas H. Perez, M.P.H.
Executive Secretary
- 8:15 **Recap of Day 1**
- 8:30 **Discussion of Questions to Committee**
- 12:00 **Adjourn**