

Pediatric Advisory Subcommittee of the Anti-Infective Drugs Advisory Committee

Food and Drug Administration
Center for Drug Evaluation and Research
Advisory Committee Conference Room, Rm. 1066, 5630 Fishers Lane, Rockville, MD.

Development of Antiretroviral Drugs in HIV-Infected and HIV-Exposed Neonates Younger than four weeks of age, and Update to the Committee on Adverse Event Reporting plan, and Pediatric Initiatives within the Agency

Agenda for March 3, 2003

Issue: Antiretroviral Drug Development in HIV-Infected and HIV-Exposed Neonates

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| 8:00 Call to Order, Introductions: | Joan P. Chesney, M.D., Chair |
| Meeting Statement: | Thomas H. Perez, R.Ph., M.P.H., Executive Secretary |
| Opening Comments: | Dianne Murphy, M.D.,
Director, Office of Pediatric Therapeutics |
| 8:20 State of the Art: Perinatal Transmission | Lynne Mofenson, M.D. |
| 8:50 Ethics of Neonatal Research | John Sever, M.D. |
| 9:10 FDA Perspective | Linda Lewis, M.D. |
| 9:30 Questions on Presentations | |
| 9:35 Break | |
| 9:50 Open Public Hearing | |
| 10:50 Discussion of Questions | |
| 12:00 Lunch | |
| 1:00 Discussion of Questions | |
| 2:15 Break | |

Issue: Pediatric Update

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| 2:30 Overview: Division of Pediatric Drug Development
Office of Pediatric Therapeutics | Dianne Murphy, M.D. |
| 2:45 Medwatch – Office of Drug Safety
Adverse Event Reporting | Solomon Iyasu, M.D. |
| 4:00 Division of Pediatric Drug Development - Update | Shirley Murphy, M.D. |
| 4:20 New Exclusivity / Rule Statistics | Terrie Crescenzi, R.Ph. |
| 4:45 Adjourn | |