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

March 3, 2003

DRAFT AGENDA

Issue: Antiretroviral Drug Development in HIV-infected and HIV-exposed Neonates

8:00 Welcome/Introductions

8:20 State of the Art/Perinatal Transmission

8:50 Ethics of Neonatal Research

9:10 FDA Perspective

9:30 Presentation of Questions

9:35 Break

9:50 Open Public Hearing

10:50 Discussion

12:00 Lunch

1:00 Discussion

2:15 Break

Issue: One-Year Post-Pediatric Exclusivity Adverse Event Reporting

2:30 Office of Pediatric Therapeutics, BPCA [Sec 6].

2:35 Adverse Events Reporting, BPCA [Sec 17]

2:40 Exclusivity Process

2:45 Overview of FDA's Adverse Events Reporting System

3:00 One-Year Post-Pediatric Exclusivity Adverse Events Reporting Plan

3:15 Adverse Events Report: Example

3:25 Questions and Answers

3:45 Exclusivity/Rule Update

4:45 Adjourn