AGENDA
OPEN SESSION
Antiviral Drugs Advisory Committee Meeting
Center for Drug Evaluation and Research
Food and Drug Administration
Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD
Monday, October 4, 1999

Topic: Issues related to the potential applicability of information from non-U.S. studies of prevention of perinatal human immunodeficiency virus transmission to U.S. clinical settings.

8:00 a.m.	Call to Order Conflict of Interest Statement -	Scott Hammer, M.D., Chair Rhonda Stover, R.Ph., Executive Secretary
8:05. a.m.	FDA Introduction	Heidi Jolson, M.D., M.P.H., Division Director, Division of Antiviral Drug Products, Office of Drug Evaluation IV, FDA
8:15 a.m.	Presentations	
	1. Epidemiology of Mother-to-Child Transmission of HIV in the U.S. and USPHS Task Force Recommendations	Catherine M. Wilfert, M.D., Professor Emerita Duke University Medical Center
	2. Overview of Clinical Trials	Lynne M. Mofenson, M.D., Associate Branch Chief for Clinical Research, NICHD/CRMC/PAMA National Institutes of Health
	3. Conduct of Trials in Developing Nations.	Stefan Z. Wiktor, M.D., Centers for Disease Control and Prevention
	4. Safety Considerations	David Morse, Ph.D. Division of Antiviral Drug Products Office of Drug Evaluation IV, FDA
10:10 a.m.	BREAK	
10:30 a.m.	Regulatory Considerations in the Development of Drugs to Prevent Perinatal Transmission of HIV.	Debra Birnkrant, M.D., Deputy Director Division of Antiviral Drug Products, Office of Drug Evaluation IV, FDA
10:45 a.m.	Discussion	
12:00 p.m.	LUNCH	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Adjourn	

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