

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC) MEETING

Draft Agenda

August 20, 2003

Holiday Inn, Versailles Ballroom, 8120 Wisconsin Avenue, Bethesda, MD 20814

Clinical Trial Design Issues
in the Development of Topical Microbicides
for the Reduction of HIV Transmission

8:00 a.m.	Call to Order	Roy M. Gulick, M.D., M.P.H. Chair, AVAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
8:15 a.m.	Opening Remarks	Debra B. Birnkrant, M.D. Director Division of Antiviral Drug Products, (DAVDP), FDA
8:30 a.m.	HIV and STIs in Women: The Urgent Need for an Efficacious Microbicide	Salim S. Abdool Karim, M.D., Ph.D. University of Natal Durban, South Africa
8:50 a.m.	Lessons Learned from COL-1492, a Nonoxynol-9 Vaginal Gel Trial	Lut Van Damme, M.D., M.Sc. Contraceptive Research and Development Program (CONRAD) Arlington, VA
9:10 a.m.	Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, a Regulatory Perspective	Teresa C. Wu, M.D., Ph.D. Medical Officer DAVDP, FDA
9:30 a.m.	Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, an Investigator's Perspective	Andrew Nunn, M.Sc. Medical Research Center London, UK
9:50 a.m.	Questions from the Committee	
10:05a.m.	Break	

10:25 a.m.	Statistical Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, an Investigator's Perspective	Thomas Fleming, Ph.D. Chair, Department of Biostatistics University of Washington Seattle, WA
10:50 a.m.	Statistical Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, a Regulatory Perspective	Rafia Bhore, Ph.D. Mathematical Statistician Division of Biometrics FDA
11:15 a.m.	Questions from the Committee	
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
1:45 p.m.	Charge to the Committee/ Questions for Discussion	Debra B. Birnkrant, M.D.
5 p.m.	Adjourn	