

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

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 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. Director, Centre for the AIDS Programme of Research in South Africa 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. International Clinical Research Manager Contraceptive Research and Development Program (CONRAD) Arlington, Virginia
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 Division of Antiviral Drug Products FDA
9:30 a.m.	Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, an Investigator's Perspective	Andrew Nunn, M.Sc. Head, Division Without Portfolio Medical Research Council Clinical Trials Unit London, United Kingdom
9:50 a.m.	Questions from the Committee	

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| 10:05a.m. | Break | |
| 10:25 a.m. | Statistical Considerations for Topical Microbicide Phase 2 and 3 Trial Designs, an Investigator's Perspective | Thomas R. Fleming, Ph.D.
Professor and Chair
Department of Biostatistics
University of Washington
Seattle, Washington |
| 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 | |
| 2:00 p.m. | Charge to the Committee/
Questions for Discussion | Debra B. Birnkrant, M.D. |
| 5:00 p.m. | Adjourn | |