

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

**DRAFT AGENDA**

May 14, 2003

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

sNDA 20-550/S-019, Valtrex<sup>®</sup> (valacyclovir hydrochloride) Caplets, GlaxoSmithKline, proposed for reduction of the risk of transmission of genital herpes with the use of suppressive therapy

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.	<b>Opening Remarks</b>	Debra B. Birnkrant, M.D. Director Division of Antiviral Drug Products FDA
8:30 a.m.	<b>Overview of Genital Herpes</b>	FDA Guest Speaker
9:00 a.m.	<b>Sponsor Presentation</b>	GlaxoSmithKline
	Introduction	David M. Cocchetto, Ph.D. U.S. Regulatory Affairs
	Study Design, Methods, and Results	Stuart M. Harding, M.D. Clinical Development and Medical Affairs
	Concluding Remarks	Clarence L. Young, M.D. Clinical Development and Medical Affairs
9:45 a.m.	Questions from the Committee	
10:00 a.m.	Break	
10:15 a.m.	<b>FDA Presentation</b>	Harry Haverkos, M.D. Medical Officer Division of Antiviral Drug Products
		Fraser Smith, Ph.D. Statistical Reviewer Division of Biometrics III

- 11:00 a.m. Questions from the Committee
- 11:15 a.m. Open Public Hearing
- 12:15 p.m. Lunch
- 1:15 p.m. Charge to the Committee/Questions for Discussion Debra B. Birnkrant, M.D.
- 4:00 p.m. Adjourn