

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

**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>Public Health Aspects of Genital Herpes</b>	H. Hunter Handsfield, M.D. Professor of Medicine University of Washington Director, STD Control Program Public Health – Seattle & King County
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	