

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

AGENDA
February 27, 2001

Holiday Inn –Gaithersburg, Maryland

NDA 21-304, valganciclovir hydrochloride tablets, 450mg, Syntex (USA) LLC, proposed for treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS).

9:00 a.m.	Call to Order	Roger J. Pomerantz, M.D. Acting Chair, AVAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm.D. Executive Secretary, AVAC
9:15 a.m.	Introduction/Opening Remarks	Debra Birnkrant, M.D. Acting Director Division of Antiviral Drug Products, FDA
9:30 a.m.	Approved Products for the Treatment of CMV Retinitis in Immunocompromised Patients	William Boyd, M.D. Medical Officer Division of Anti-Inflammatory, Analgesic, and Ophthalmologic Drug Products, FDA
9:45 a.m.	Sponsor Presentation	Syntex (USA) LLC
	Introduction	Mary Jean Stempien, M.D., M.S. Director, Medical Research, Roche
	Clinical Background	Daniel F. Martin, M.D. Associate Professor of Ophthalmology Emory University School of Medicine
	Development Program & Study Results	Mary Jean Stempien, M.D., M.S.
10:30 a.m.	Questions from the Committee	
10:45 a.m.	Break	
11:00 a.m.	FDA Presentation	Joseph Toerner, M.D. Medical Officer Division of Antiviral Drug Products
		Robert Kumi, Ph.D. Pharmacokinetics Reviewer Division of Pharmaceutical Evaluation III

11:45 a.m. Questions from the Committee

12:00 p.m. Lunch

1:00 p.m. Open Public Hearing

Michael Marco – Treatment Action Group (TAG)

2:00 p.m. Committee Discussion and Vote

5:30 p.m. Adjourn