

FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)
ANTIVIRAL DRUGS ADVISORY COMMITTEE (AVAC)
IMMUNOSUPPRESSIVE DRUGS SUBCOMMITTEE MEETING

AGENDA

January 24, 2002
Gaithersburg Holiday Inn
Two Montgomery Village Avenue
Gaithersburg, MD 20879

NDA 21-083 Rapamune® (sirolimus) Oral Solution – Cyclosporine Withdrawal
Maintenance Regimen

8:30 a.m.	Call to Order and Opening Remarks	Janet A. Englund, M.D. Subcommittee Chair
	Introduction of Subcommittee	
	Conflict of Interest Statement	Tara P. Turner, Pharm. D. Executive Secretary, AVAC
8:40 a.m.	FDA Introductory Remarks	Renata Albrecht, M.D. Acting Director Division of Special Pathogen and Immunologic Drug Products, FDA
8:45 a.m.	Sponsor Presentation	Wyeth-Ayerst Research
	Introduction	Randall B. Brenner, M.S. Senior Manager Worldwide Regulatory Affairs
	Overview	John F. Neylan, M.D.
	Design of Clinical Studies	Vice President
	Efficacy Review	Transplantation Immunology,
	Safety Review	Clinical Research and Development
	Pharmacokinetics	James Zimmerman, Ph.D.
	Concentration-Controlled Trials	Senior Director
	Therapeutic Drug Monitoring	Clinical Pharmacokinetics, Clinical Research and Development
	Concluding Remarks	John F. Neylan, M.D.
10:45 a.m.	Break	

11:00 a.m.	FDA Presentation	Rosemary Tiernan, M.D., M.P.H. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
		Alan Wilkinson, M.D., F.R.C.P. Director, Kidney and Pancreas Transplantation Professor of Medicine UCLA
2:00 p.m.	Charge to the Subcommittee	Renata Albrecht, M.D.
2:10 p.m.	Subcommittee Discussion and Vote	
5:00 p.m.	Adjourn	