

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

TENTATIVE AGENDA

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

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

8:30 a.m.	Call to Order and Opening Remarks	Chair, AVAC, Subcommittee for Immunosuppressants
	Introduction of Committee 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
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 (Tentative Speaker)
12:00 p.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	Renata Albrecht, M.D. Acting Director Division of Special Pathogen and Immunologic Drug Products, FDA

2:10 p.m. Committee Discussion and Vote

5:00 p.m. Adjourn