

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

**AGENDA**  
October 4, 2001

The Town Center Hotel –Silver Spring, Maryland

NDA 21-266, Vfend™ (voriconazole) Tablets and NDA 21-267, Vfend™ I.V. (voriconazole) for Injection, Pfizer Global Research and Development, proposed for the treatment of invasive aspergillosis, serious *Candida* infections, infections caused by *Scedosporium* spp. and *Fusarium* spp., rare and refractory infections, and empirical antifungal therapy in febrile neutropenic patients.

8:30 a.m.	Call to Order and Opening Remarks	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
8:40 a.m.	<b>FDA Introductory Remarks</b>	Mark Goldberger, M.D., M.P.H. Acting Director Office of Drug Evaluation IV, FDA
8:45 a.m.	<b>Sponsor Presentation</b>	Pfizer Global Research and Development
	Introduction	Reinhard Baildon, M.D. Executive Director Clinical Development
	Invasive Fungal Infections: Management and Medical Need	Thomas F. Patterson, M.D. The University of Texas Health Science Center at San Antonio
	InVitro/InVivo Data Clinical Pharmacology	Reinhard Baildon, M.D.
	Efficacy	Helen W. Boucher, M.D. Senior Associate Director Clinical Development
	Safety and Conclusions	Reinhard Baildon, M.D.
10:45 a.m.	Break	

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11:00 a.m.	<b>FDA Presentation</b>	Rosemary Tiernan, M.D., M.P.H. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
		John Powers, M.D. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
12:30 p.m.	Lunch	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Charge to the Committee	Mark Goldberger, M.D., M.P.H.
2:40 p.m.	Committee Discussion and Vote	
5:00 p.m.	Adjourn	