

FOOD AND DRUG ADMINISTRATION
Center for Drug Evaluation and Research
ANTI-INFECTIVE DRUGS ADVISORY COMMITTEE (AIDAC) MEETING

AGENDA
October 28, 2003

Holiday Inn, The Ballrooms, Two Montgomery Village Avenue, Gaithersburg, MD

Topic: Clinical trial design in Diabetic Foot Infections

1:00 p.m.	Call to Order	James E. Leggett, Jr., M.D. Chair, AIDAC
	Introduction of Committee	
	Conflict of Interest Statement	Tara P. Turner, Pharm. D. Executive Secretary, AIDAC
1:10 p.m.	Overview: Antimicrobial Development for Diabetic Foot Infections	Janice Soreth, MD Director Division of Anti-Infective Drug Products FDA
1:20 p.m.	Diabetic Foot Infections: Overview	Dr. Tony Berendt, BM, BCh, FRCP Bone Infection Unit Nuffield Orthopaedic Centre, Oxford, UK
1:40 p.m.	Clinical trials consideration in DM foot infections	Carl Norden, M.D. Medical Director Pfizer Inc.
2:00 p.m.	Lessons Learned from Previous Review of Drugs for Diabetic Foot Infections	Alfred Sorbello, D.O. Medical Officer Division of Anti-Infective Drug Products FDA
2:20 p.m.	Microbiologic Diagnosis of Diabetic Foot Infections	Albert Sheldon, Ph.D. Microbiology Team Leader Division of Anti-Infective Drug Products FDA
2:40 p.m.	Ruling Out Osteomyelitis in Trials of Diabetic Foot Infections	Regina Alivisatos, M.D. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA
3:00 p.m.	Implications for Clinical Trials for Diabetic Foot Infections	David Ross, M.D., Ph.D. Medical Team Leader Division of Anti-Infective Drug Products FDA
3:15 p.m.	Break	

3:25 p.m.	Open Public Hearing	
3:55 p.m.	Charge to the Committee	Edward Cox, M.D., M.P.H. Deputy Director Office of Drug Evaluation IV, FDA
4:00 p.m.	Committee Discussion	
5:30 p.m.	Adjourn	

QUESTIONS TO THE COMMITTEE

1. How does one define a “diabetic foot infection”? Please include in your discussions the considerations of patients with cellulitis without breaks in the skin versus patients with pre-existing breaks in the skin.
2. In patients with a pre-existing skin ulcer, how does one define infected versus non-infected ulcers?
3. What is the most accurate way to obtain microbiologic information in patients with diabetic foot infections?
4. What are the considerations for clinical trials for ruling out osteomyelitis in patients in trials of diabetic foot infections? Please discuss how to determine drug efficacy for the diabetic foot infection in the setting of osteomyelitis and whether such patients should be considered clinical cures or failures.
5. How does one define clinical success or failure patients in a clinical trial of diabetic foot infections?