

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

Questions
October 28, 2003

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

Topic: Clinical trial design in Diabetic Foot Infections

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?