

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

**Questions**  
October 29, 2003

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

Topic: Clinical trial design in Acute Bacterial Sinusitis (ABS)

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**QUESTIONS TO THE COMMITTEE**

1. How does one ensure that patients in clinical trials of acute bacterial sinusitis have bacterial disease? Please discuss the methods of obtaining microbiologic data including sinus punctures and nasal endoscopy.
2. Please discuss the issues of trial design in the study of acute bacterial sinusitis. Please include in your discussion:
  - a. the strengths and limitations of placebo-controlled trials and non-inferiority trials. Please discuss how one determines a non-inferiority margin in non-inferiority trials for this indication.
  - b. the strengths and limitations of comparative microbiologic data.
3. Please discuss the issues of measuring outcomes in patients in trials of acute bacterial sinusitis. Please include in your discussion measuring time-to-resolution of symptoms as an endpoint compared to fixed endpoints.