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

AGENDA

October 29, 2003

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

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

8:30 a.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
8:40 a.m.	**General Overview: Antimicrobial Development for ABS, Regulatory History**	Renata Albrecht, M.D. Director Division of Special Pathogen and Immunologic Drug Products, FDA
9:00 a.m.	**Acute Bacterial Sinusitis: Overview**	Jack M. Gwaltney, Jr., M.D. Professor Emeritus, Division Head Division of Epidemiology and Virology University of Virginia
9:40 a.m.	**Description of Sinus Puncture**	Thomas A. Sydnor, Jr., M.D. Otolaryngologist Virginia Medical Studies (Retired)
10:00 a.m.	**Statistical Considerations in Clinical Trial Design in ABS**	Thomas R. Fleming, Ph.D. Professor and Chair Department of Biostatistics University of Washington
10:30 a.m.	Break	
10:45 a.m.	**Clinical Evaluation of ABS: Diagnostic Considerations**	Carl Kraus, M.D. Medical Officer Division of Special Pathogen and Immunologic Drug Products, FDA

11:15 a.m.	**Lesson Learned from Clinical Trial Design in Past Approvals**	Janice Pohlman, M.D. Medical Officer Division of Anti-Infective Drug Products FDA
11:45 a.m.	**Clinical Trial Design in ABS: Considerations for Future Guidance**	John H. Powers, M.D. Lead Medical Officer for Antimicrobial Drug Development Office of Drug Evaluation IV, FDA
12:15 p.m	Lunch	
1:15 p.m.	Open Public Hearing	
1:45 p.m.	Charge to Committee	Edward Cox, M.D., M.P.H. Deputy Director Office of Drug Evaluation IV, FDA
1:50 p.m.	Committee Discussion	
4:30 p.m.	Adjourn	

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.