

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

QUESTIONS TO THE COMMITTEE

February 20, 2002

Holiday Inn, Two Montgomery Village Avenue, Gaithersburg, MD

Topic: Approaches to the development of antimicrobial agents for the treatment of resistant pathogens

Based upon the presentations at this meeting and your knowledge and experience in the field, please discuss the following issues regarding drug development for resistant pathogens:

1. What are the barriers/challenges that hinder drug development for resistant pathogens? In your discussion please consider the following types of development programs:
 - an out-of-class resistance claim (e.g., quinolone for PRSP)
 - an in-class (or class-related) resistance claim (e.g., beta-lactam for PRSP)
 - a resistant pathogen with moderate to high prevalence
 - an emerging resistant pathogen of low prevalence

How do we overcome these challenges and barriers while assuring that drugs are shown to be safe and effective for their intended use?

2. Based upon the presentation from this morning, please comment on a focused drug development approach for resistant pathogens. In your discussion, please discuss the following:
 - the likelihood that a focused development program will provide sufficient data to address safety and efficacy
 - the role of data from treating sensitive strains of the pathogen of interest to support an out-of-class, an in-class, or a class-related resistance claim
 - the role of non-clinical data and/or PK/PD data
 - the possible incentives for developing drugs for resistant pathogens
3. Please discuss any alternative strategies or approaches the Committee wishes to propose for the development of drugs for the treatment of resistant pathogens.
4. Please discuss strategies or approaches the Committee wishes to propose for “preserving the efficacy” of currently marketed antimicrobials, i.e., to prevent development of antimicrobial resistance.