

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

**QUESTIONS TO THE COMMITTEE**  
January 8, 2003

Marriott Washingtonian Center, Grand Ballroom, 9751 Washingtonian Blvd., Gaithersburg, MD

NDA 21-144, Ketek™ (telithromycin), Aventis Pharmaceuticals, Inc., proposed for treatment of community-acquired pneumonia, acute exacerbation of chronic bronchitis, and acute maxillary sinusitis

1. Do the safety and effectiveness data presented support the use of Ketek™ (telithromycin) for the following indications?
  - a. Community acquired pneumonia
  - b. Acute exacerbation of chronic bronchitis
  - c. Acute sinusitis

If yes, are there any special caveats that should be included in the label?

If no, what other information would be required?

2. Do the safety and effectiveness data presented support the use of Ketek™ (telithromycin) for the treatment of penicillin-resistant *S. pneumoniae* for the following indications?
  - a. Community acquired pneumonia
  - b. Acute sinusitis

If yes, are there any special caveats that should be included in the label?

If no, what other information would be required?

3. Do the safety and effectiveness data presented support the use of Ketek™ (telithromycin) for the treatment of macrolide-resistant *S. pneumoniae* for the following indications? Please consider in your discussion the public health impact of macrolide-resistant *S. pneumoniae*.
  - a. Community acquired pneumonia
  - b. Acute sinusitis

If yes, are there any special caveats that should be included in the label?

If no, what other information would be required?

4. Are there any additional studies of Ketek™ you would recommend?