

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

**QUESTIONS TO THE COMMITTEE**

March 4, 2003

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

NDA 21-158, Factive<sup>®</sup> (gemifloxacin) Tablets, Parexel International, U.S. Agent for LG LifeSciences, Ltd., proposed for the treatment of community acquired pneumonia and acute bacterial exacerbation of chronic bronchitis

1. Based on the data presented and in your scientific and clinical opinion, do the benefits of gemifloxacin therapy outweigh the risks for the proposed indications of:
  - (a) Community acquired pneumonia
  - (b) Acute bacterial exacerbation of chronic bronchitis

Please include as part of your discussion:

- The clinical and microbiologic benefits of gemifloxacin
  - The significance of the rash, particularly as it relates to the likelihood of more severe dermatological manifestations with broader use and the likelihood of cross-sensitization to other fluoroquinolones.
  - The hepatic toxicity profile of the drug
2. If the answer to question (1a/1b) is yes, please discuss the types of information that should be provided to physicians and patients. Please focus on the elements outlined in question 1 as well as any other issues you believe relevant. Please include as part of this discussion any caveats as to how and to whom the drug should be administered. For any risk communication/management strategy that may be appropriate, please comment on how practical and/or effective such strategies may be.
  3. If the answer to (1a/1b) is no, please recommend what additional studies or information should be obtained for
    - (a) Community acquired pneumonia
    - (b) Acute bacterial exacerbation of chronic bronchitis