

**FDA ADVISORY COMMITTEE QUESTIONS:
TELITHROMYCIN**

4/26/01

- I. Given the risks of cardiac and hepatic toxicity of telithromycin, does the efficacy for telithromycin in respiratory infections supports its use for:
- community acquired pneumonia;
 - acute exacerbation of chronic bronchitis;
 - acute sinusitis?

In your discussion please comment on the following:

- A. Has the applicant provided sufficient data to warrant a claim for the treatment of community-acquired pneumonia due to penicillin-resistant *S. pneumoniae* (PRSP)?
- If NO, what additional studies should be conducted?
- B. Is there sufficient evidence that an infection due to erythromycin-resistant *S. pneumoniae* (ERSP) has a negative impact on clinical outcome compared to that of sensitive strains of *S. pneumoniae*?
- If YES, has the applicant provided sufficient data to warrant a claim for the treatment of community acquired pneumonia due to erythromycin-resistant *S. pneumoniae* (ERSP)?
 - Comment on the potential for concurrent-resistance of telithromycin and the macrolide antimicrobials?
- C. If the committee recommends approval, should this approval involve restrictions? For example, restrictions in the label use in special populations only, limitations in access or distribution.
- II. If the committee has not recommended approval, please provide recommendations for additional studies if appropriate.