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

QUESTIONS TO THE COMMITTEE

July 10, 2002

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

NDA 21-242, Artesunate Rectal Capsules, World Health Organization, proposed for the initial management of acute malaria in patients who cannot take medication by mouth and for whom parenteral treatment is not available

1. The applicant has demonstrated the activity of artesunate by showing a decline in parasitemia over 24 hours and a 24-hour clinical outcome similar to that seen with comparator drugs in hospitalized patients with "moderately severe" malaria. Are these results sufficient to support the approval of artesunate for use as initial therapy in patients without other therapeutic alternatives?

   In your discussion, please include the usefulness of parasitemia as a measure of efficacy, the importance of recrudescence rates at Day 28, the related issue of follow-up therapy, and the importance of the differences in the study population and the intended use population.

   If your answer to the above question is "No", please indicate what additional information would be required.

2. Is the safety information and safety profile of artesunate sufficient to support the approval of artesunate for use as initial therapy in patients without other therapeutic alternatives?

   In your discussion, please include the differences in the clinical trial and the intended patient populations, addressing the potential risks and benefits in the empirical use of the product for emergency therapy.

   If your answer to the above question is "No", please indicate what additional information would be required.

3. If the answers to Questions 1 and 2 are "Yes", please indicate if there are any caveats or restrictions that should be included in the product labeling.

4. If this product were approved under Subpart H regulations (Accelerated Approval of New Drugs for Life-Threatening Illnesses), what additional studies would be required in the post-approval period?