

**Food and Drug Administration
Center for Drug Evaluation and Research**

Arthritis Advisory Committee

Gaithersburg Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg, MD

**(Draft) Questions
February 7, 2001**

NDA # 20-998/S009, Celebrex™ (celecoxib, Searle)

- 1. Has a clinically meaningful safety advantage been established for Celebrex compared to ibuprofen and/or diclofenac? Please respond specifically for UGI safety and separately for global safety.**
- 2. In subjects taking low dose aspirin there was a reverse trend in results for both the complicated ulcer as well as combined complicated and symptomatic ulcer endpoints. Does there appear to be a safety signal in this database regarding concomitant use of COX-2 selective agents and aspirin?**
- 3. Are further studies warranted regarding concomitant aspirin and COX-2 selective/ traditional NSAIDs?**
- 4. Considering the results of the CLASS trial, do the current NSAID related target organs for toxicity in the current NSAID template remain applicable? (GI, renal/fluid retention, hepatic and skin). See attached template. Please discuss.**