

**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 8, 2001**

NDA # 21-042/S007, Vioxx™ (Rofecoxib, Merck)

- 1. Please comment on the differences in cardiovascular event rates between the Vioxx 50 mg and naproxen groups. Are further studies warranted? Does this finding warrant consumer/prescriber awareness? If so, in what format?**
- 2. Given the potential effects of concomitant aspirin use on GI and cardiovascular outcomes and the large population of patients for whom both anti-platelet and analgesic/anti-inflammatory agents are indicated, what guidance should be given at this time regarding the concomitant use of aspirin and VIOXX? Are additional studies warranted?**
- 3. Considering the results of the VIGOR 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.**
- 4. Please comment on the overall safety comparisons between Vioxx and naproxen in the VIGOR study.**