

NONPRESCRIPTION DRUGS  
ADVISORY COMMITTEE AND  
ARTHRITIS ADVISORY  
COMMITTEE

JULY 20, 1999

NDA 21070

QUESTIONS

**Nonprescription Drugs Advisory Committee  
Arthritis Advisory Committee  
July 20, 1999**

NDA 21-070, Flexeril®, cyclobenzaprine HCl, Merck

Questions

**DRAFT**

1. The data in the original NDA support the use of a Flexeril dose of 10 mg T.I.D. (in the range of 20-40 mg total daily dose) as a prescription product. In the current submission for OTC use, do both Study 006 and Study 008 demonstrate a clinically significant effect of Flexeril 5 mg T.I.D. for relief of painful muscle tightness and spasm of the back or neck due to recent strain, overuse, or minor injury? In answering this question please describe the end-points and analyses that caused you come to your conclusion.
2. Is muscle spasm of the back or neck a consumer self-diagnosable condition? In answering this question please describe the data relied upon from the application.
3. Can consumers identify when Flexeril should be used, as opposed to other products such as an OTC analgesics?
  - a) Can they adequately assess whether their condition is responding to treatment?
  - b) Were there conditions identified by a significant number of subjects where Flexeril use was considered when it should not have been?
4. Has the metabolism and excretion of Flexeril been adequately characterized?
  - a) If no, what additional information should be obtained (e.g. better characterization of the metabolic pathway, drug-drug interactions)?
  - b) Are there any potential or known drug-drug or drug-food interactions that may impact on the safe use of this drug in the OTC setting?
5. Safety concerns include the adverse reactions associated with Flexeril use (especially adverse reactions similar to those seen with closely-related tricyclic antidepressants); the possibility of misuse or overdose; and any possible drug interactions.
  - a) Can consumers, including elderly individuals, safely use Flexeril in an OTC setting, taking into account the available data on adverse effects, sedation, overdose and misuse, and concomitant medications?
  - b) If not, why not? If yes, is any additional information needed on the labeling?
6. Does the Committee have any additional concerns/issues?