

Questions

Psychopharmacological Drugs Advisory Committee

Holiday Inn, Bethesda, Maryland
May 10, 2002

NDA 21-431: Acamprosate 333 mg tablets (Lipha Pharmaceuticals, Inc.)

The committee is asked to consider the evidence of efficacy of acamprosate in the treatment of alcoholism and to provide advice on the following questions:

- 1. How can the discrepant results between the older, European studies and the more recently conducted American study be reconciled?**
- 2. Do the data support any conclusions regarding subgroups of patients more likely to benefit from acamprosate?**
- 3. Given the conflicting results, is there sufficient evidence of the efficacy of acamprosate in the treatment of alcoholism to warrant approval?**