

Psychopharmacologic Drugs Advisory Committee
May 10, 2002

Questions for Discussion

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. Given the conflicting results between the older, European studies and the more recently conducted American study, is there sufficient evidence of the efficacy of acamprosate in the treatment of alcoholism to warrant approval?
2. How can the discrepant results be reconciled? Do the data support any conclusions regarding subgroups of patients more likely to benefit from acamprosate?
3. Should additional clinical studies be undertaken to evaluate the responsiveness of the US alcoholic population to acamprosate at higher doses?