

**Food And Drug Administration
Center For Biologics Evaluation And Research
Vaccines And Related Biological Products Advisory Committee Meeting
Wednesday, September 22, 2004**

Questions for the Committee

1. Are the available data adequate to support the efficacy of Menactra, i.e., non-inferiority of the antibody response to Menactra compared to the licensed polysaccharide, Menomune, when administered to individuals 11-55 years of age? If not, what additional data are necessary?
2. Are the available data adequate to support the safety of Menactra when administered to individuals 11-55 years of age? If not, what additional data are necessary?
3. Please discuss the adequacy of the data regarding of the use of Menactra with other vaccines likely to be concurrently administered, e.g. Td.
4. Please identify any issues that should be addressed in post-licensure studies.