Food and Drug Administration

Center for Drug Evaluation and Research (CDER)

Advisory Committee for Reproductive Health Drugs

December 15, 2003

Hilton Grand Ballroom
620 Perry Parkway, Gaithersburg, MD

Questions to the Committee

1. Are further increases in folic acid intake, beyond what is available from fortified cereals, likely to result in public health advances in preventing further neural tube defects?

2. Can we define a subpopulation among women of reproductive age that needs additional folic acid? If yes, what subpopulation should receive additional folic acid and how would you identify this population?

3. Are there any safety issues associated with folic acid supplementation targeted at reproductive-age women? If so,
   a. What are they?
   b. Would these safety issues not be a concern below a certain level of supplementation? If so, what is that level?

4. Would the benefit of prior folic acid use persist if conception occurs after discontinuation of folic acid? If so, for how long will the benefit persist?

5. Is an oral contraceptive pill a reasonable delivery vehicle if additional folic acid supplementation is likely to provide public health advances in preventing further neural tube defects?
   a. If so, would 400 mcg be a reasonable dose?
   b. If 400 mcg is not appropriate, what dose of folic acid should be provided?