Food and Drug Administration
Center for Drug Evaluation and Research

Nonprescription Drugs Advisory Committee (NDAC)
in joint session with the
Advisory Committee for Reproductive Heath Drugs (ACRHD)

Hilton, 620 Perry Parkway, Gaithersburg, Maryland

December 16, 2003

Questions to the Committee

1. Does the Actual Use Study (AUS) demonstrate that consumers used the product as recommended in the proposed labeling?

2. Are the AUS data generalizable to the overall population of potential non-Rx users of Plan B?

3. Based on the AUS and literature review, is there evidence that non-Rx availability of Plan B leads to substitution of emergency contraception (EC) for the regular use of other methods of contraception?

4. Do the data demonstrate that Plan B is safe for use in the non-prescription setting?

5. Are the plans for introduction of Plan B into the non-Rx setting adequate with respect to consumer access and safe use? If no, what other options would you recommend?

6. Do you recommend Plan B be switched from Rx to non-Rx status?

   If yes, any modifications to labeling or distribution?

   If no, what additional information would be required?