Reproductive Health Drugs Advisory Committee

FDA Technical Center
Gaithersburg MD
19 July 1996

QUESTIONS

The regimen proposed for the use of mifepristone for the termination of early pregnancy consists of the oral administration of 600 milligrams of mifepristone within 49 days after the beginning of the last menstrual period, followed by oral administration of 400 micrograms of misoprostol 48 hours later.

1. a. Do the results of the open-label, historically controlled studies conducted in France establish the efficacy of this regimen for use in the United States?
   b. If not, what additional efficacy information should the applicant provide?
2. The safety database for this regimen consists of trials conducted in France, preliminary data from U.S. trials, and foreign post-marketing experience.
   a. Do these data adequately demonstrate that the regimen is safe for use in the United States when used for the proposed indication?
      In your discussion, please include comments on the following issues:
      - *Whether the adverse events associated with the regimen can be adequately managed when the regimen is administered as labeled.*
      - *The acceptability of the frequency of adverse events.*

   b. If not, what additional safety information should the applicant provide?
3. Taking into consideration the overall evidence for safety and effectiveness of the regimen, do you believe the benefits outweigh the risks for use of the regimen for the proposed indication in the United States?
4. If the regimen were to be approved, do you consider the labeling proposed by the applicant on how to administer the regimen and how to monitor patients who receive it to be appropriate?
5. If the regimen were to be approved, what further information, if any, do you recommend be included in the written information to be provided to the patient?
6. If the regimen were to be approved, do you have recommendations concerning the drug distribution system proposed by the applicant?
7. If the regimen were to be approved, what recommendations, if any, do you have for post-marketing studies?