Food and Drug Administration
Center for Drug Evaluation and Research
Dermatologic and Ophthalmic Drugs Advisory Committee
Holiday Inn, 2 Montgomery Village Avenue, Gaithersburg

September 18, 2000

Questions to the committee

Considerations from a Risk Management Perspective
Pregnancy Prevention Program

Question 1

The Agency has outlines three goals for a successful risk management program for Accutane®:

1. No one should begin Accutane® therapy if pregnant
2. No pregnancies should occur while on Accutane® therapy
3. Implementation of a monitoring program to ensure the above goals are met.

Does the Committee agree with these goals?

Are there others that you would recommend?

Question 2

Of the five Designs presented by FDA, which is the most likely to achieve the stated goals while balancing the associated burdens? Please discuss why you chose this design.

Question 3

How can FDA best monitor the impact of the Pregnancy Prevention Program? Possible options include:

1. Registration of additional parties (patients or pharmacists).
2. Obtaining data on compliance with the program.
3. Utilizing an external monitoring program to assess pregnancy exposures and outcomes.

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Considerations from a Risk Management Perspective
Accutane® Associated Psychiatric Adverse Events

Question 1

Is there sufficient concern to justify more risk management? If yes, what additional messages need to be communicated and in what form?

Possible considerations include:

Education & Information
- Information for Health Care Professionals
  - CME Programs
  - Professional labeling
- Information for Patients
  - Patient Package insert (optional)
  - Brochure (optional)
  - Medication Guide (requited distribution
- Informed Consent

Intervention
- Monitoring of Patients
- Management of Events
- Drug Distribution
- Prospective controlled trial

Question 2

Would further studies help to clarify the relationship between Accutane® use and psychiatric events? If so, what kind of studies.

Possible considerations include:
- Basic science research
- Open Cohort Study (survey)
- Retrospective epidemiologic cohort study
- Prospective controlled trial

Considerations from a Risk Management Perspective

Accutane® New Formulation (NDA 21-177)

Question 1

Given the data presented, does the Committee feel further dose-ranging studies are needed for Accutane®? If so, please discuss possible study designs.

Question 2

Does the Committee believe that there may be possible consequences associated with the simultaneous marketing of Accutane® and the new formulation for both prescribers and patients? If yes, please comment on appropriate strategies to alleviate them.