Food and Drug Administration
Center for Drug Evaluation and Research
8/1/07
Dermatologic and Ophthalmic Drugs Advisory Committee
(DODAC)
in joint session with the
Drug Safety and Risk Management Advisory Committee
(DSaRM)

The Dermatologic and Ophthalmic Drugs and the Drug Safety and Risk Management Advisory Committees will meet in joint session to be briefed on iPLEDGE, the risk management program for isotretinoin products. Presentations will provide updates on risk management activities for isotretinoin since the full implementation of iPLEDGE on March 1, 2006.

Questions to the committee:

1. The changes proposed in the pending supplement are intended to increase program flexibility and to reduce interruptions of treatment. Please discuss and vote on whether the proposed changes are acceptable.

2. Discuss approaches to enhancing voluntary participation in the pregnancy registry within the iPLEDGE program.

3. Are there additional recommendations for the future to address the risk management functions of the iPLEDGE program?