

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)
and the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)*

FDA White Oak Campus, Building 31, the Great Room,
White Oak Conference Center (Room 1503), Silver Spring, MD
December 1, 2011

QUESTIONS TO THE COMMITTEES

Discussion Questions Morning Session:

1. Discuss whether iPLEDGE continues to assure the safe use of isotretinoin in particular, discuss the extent to which iPLEDGE is imparting needed knowledge and ensuring good clinical practices to prevent fetal exposure.
2. Discuss whether iPLEDGE is unduly burdensome on patients who require access to isotretinoin therapy.
3. Discuss if there are ways, to the extent practicable, to minimize the burden of iPLEDGE on healthcare delivery.