

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

FOOD AND DRUGS ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH
ADVISORY COMMITTEE CONFERENCE ROOM
5630 FISHERS LANE ; ROCKVILLE, MARYLAND

QUESTIONS TO ADVISORY COMMITTEE

May 29, 2008

1. Do you think difluprednate ophthalmic emulsion should be approved for the treatment of ocular inflammation and pain following cataract surgery?
2. If no, what additional studies should be performed?
3. If yes, any additional Phase 4 studies should be performed?
4. Do you have any suggestions concerning the labeling of the product?