

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

Dermatologic and Ophthalmic Drugs Advisory Committee Meeting

HILTON WASHINGTON DC /ROCKVILLE
ROCKVILLE, MARYLAND

QUESTIONS TO THE ADVISORY COMMITTEE

December 5, 2008

Bimatoprost Ophthalmic Solution, Allergan

1. Do you think the benefits outweigh the risks for Latisse (bimatoprost ophthalmic solution) 0.03% for the treatment of hypotrichosis of the eyelashes?
2. If not, what additional studies should be performed?
3. If yes, should any additional Phase 4 studies be performed?
4. Do you have any suggestions concerning the labeling of the product?