

Food and Drug Administration
Center for Drug Evaluation and Research
Dermatologic and Ophthalmic Drugs Advisory Committee
Holiday Inn, The Ballrooms, Montgomery Village Avenue, Gaithersburg, Maryland
September 10, 2003
DRAFT Agenda

**NDA 21-576, Methyl aminolevulinate hydrochloride, (Methyl aminolevulinate cream, 168mg/g) by PhotoCure
ASA**

8:30	Call to Order and Opening Remarks	Robert S. Stern, M.D.
	Conflict of Interest Statement	Kimberly L. Topper, M.S.
8:45	Introduction	Jonathan Wilkin, M.D.
9:00	Industry Presentation	
	Introduction	Kjetil Hestdal, M.D., Ph.D., William Clementi, Pharm.D., F.C.P.
	Regulatory Overview	
	Photodynamic therapy with methyl aminolevulinate (MAL PDT). Non-surgical Treatment of BCC	Kjetil Hestdal, M.D., Ph.D.
	Overview of Clinical Development Program of MAL PDT in BCC	Kjetil Hestdal, M.D., Ph.D.
	Efficacy in BCC: Placebo controlled studies	David M. Pariser, M.D., FACP
	Efficacy in BCC: Active controlled studies, including long term follow-up	David M. Pariser, M.D.
	Efficacy in High-Risk BCC, including long term follow-up	Prof D��d��e F Murrell MA ,BMBCh , FAAD
	Safety, including skin sensitization	John Posner, Ph.D., FRCP
	MAL PDT in BCC Benefit/risk	Kjetil Hestdal, M.D., Ph.D.
10:00	Committee Discussion	
10:30	Break	
10:45	FDA Presentation - Methyl aminolevulinate Cream (MAL) with Curettage and Photodynamic Therapy (PDT) for Nodular Basal Cell Carcinoma (BCC)	Markham Luke, M.D., Ph.D. Brenda Vaughan, M.D. Mohamed Al Osh, M.D.
11:45	Committee Discussion	
12:15	Lunch	
1:15	Open Public Hearing	
2:15	Committee Discussion	
3:15	Break	
3:30	Questions	
5:30	Adjournment	

