Food and Drug Administration
Center for Drug Evaluation and Research

Dermatologic and Ophthalmic Drugs Advisory Committee
(DODAC)
in joint session with the
Drug Safety and Risk Management Advisory Committee
(DSaRM)

Agenda

August 1, 2007

8:00	Call to Order and Opening Remarks	Chair, DODAC Michael E. Bigby, M.D.
	Introduction of Committees	Associate Professor of Dermatology Beth Israel Deaconess Medical Center Boston, MA
	Conflict of Interest Statement	LCDR Sohail Mosaddegh, PharmD., R.Ph. Designated Federal Official DODAC CDER, FDA

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.

8:10	Charge to the Committee	Susan Walker, M.D., F.A.A.D Director, Division of Dermatology and Dental Products (DDDP), CDER, FDA
8:15	Regulatory History of Isotretinoin and Program Changes	Gordana Diglisic, M.D. Medical Officer, DDDP
8:25	Design of iPLEDGE Program and Proposed Programmatic Changes	Bonnie Southorn, Ph.D, Genpharm James Shamp, Covance
8:55	Clarifying Qs & As	

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Agenda (cont.)
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9:00	iPLEDGE Program – One-Year Update	Daniel Reshef, MD, Ph.D. Hoffmann-La Roche Inc.
9:30	Perspectives on Pregnancy Registry & Patient Knowledge Assessment	Cynthia Kornegay, Ph.D. Office of Surveillance and Epidemiology
9:45	Clarifying Qs and As	Committee Members
10:00	**Break**	
10:15	Open Public Hearing	
11:15	Questions to the Committee	
12:30	Adjourn	