

**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

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|---|---|--|
| 8:00 | Call to Order and Opening Remarks | Chair, DODAC
Michael E. Bigby, M.D.
Associate Professor of Dermatology
Boston, MA |
| | Introduction of Committees | |
| | Conflict of Interest Statement | LCDR Sohail Mosaddegh
PharmD, RPh
Executive Secretary
DODAC |
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Note: 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
Dermatologic 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 | Covance speaker TBD |
| 8:55 | Clarifying Qs & As | |

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Agenda (cont.)

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| 9:00 | iPLEDGE Program – One-Year Update | Hoffmann La Roche speaker TBD |
| 9:30 | Pregnancy Registry & Root Cause Analysis | 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 | |