Food and Drug Administration
Center for Drug Evaluation and Research

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

Hilton, 620 Perry Parkway, Gaithersburg, Maryland

Agenda **February 26, 2004**

8:00	Call to Order and Opening Remarks	Peter Gross, M.D. Chair, DSaRM
	Introduction of Committee	
	Conflict of Interest Statement	Shalini Jain, PA-C, M.B.A. Executive Secretary, DSaRM

Effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to Accutane and its generic equivalents and consideration of whether changes to this isotretinoin risk management program would be appropriate

8:15	Charge to the Committees	Steven Galson, M.D., M.P.H. Acting Director, Center for Drug Evaluation and Research (CDER)
8:30	Background and Regulatory History	Jill Lindstrom, M.D. Medical Officer Division of Dermatologic and Dental Drug Products, FDA
	Questions to the Speaker from Committee	
9:30	Open Public Hearing	
9:40	**Hoffmann-La Roche, Inc. Presentations**	Joanna Waugh Group Director, Regulatory Affairs
		Martin H. Huber, M.D. Vice President, Global Head Drug Safety Risk Management
		Susan Ackermann Shiff, Ph.D. Global Head Risk Management, Drug Safety Risk Management

Food and Drug Administration
Center for Drug Evaluation and Research
Drug Safety and Risk Management Advisory Committee (DSaRM)
in joint session with the
Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)

Agenda (cont.) February 26, 2004

10:30	**Generic Firms' Presentations**	
	Isotretinoin Risk Management Program - Background Information	Frank R. Sisto, Vice President Corporate Regulatory Affairs Mylan Laboratories Inc.
	Isotretinoin Survey	Allen A. Mitchell, M.D., Director Slone Epidemiology Center Boston University
	Isotretinoin Enhanced Risk Management Program - Program Elements for Which Advisory Committee Input is Requested	Robert W. Pollock, Vice President Lachman Consultant Services Inc.
	Questions to Roche and Generic Firms from Committee	
11:45	Lunch	
1:00	Isotretinoin Pregnancy Exposure: Spontaneous Reports 1-Year pre and 1-Year post-Risk Management Program	Marilyn Pitts, Pharm.D. Safety Evaluator, FDA
	Isotretinoin Pregnancy Prevention Program Evaluation	Allen Brinker, M.D., M.S. Lead Medical Officer, Epidemiology, FDA
2:00	**Kaiser Presentation**	Richard A. Wagner, Pharm.D. Leader Kaiser Permanente Drug Use Management
	Questions to Kaiser from the Committee	
2:30	**Organization of Teratology Information Services** (OTIS), Interim Report, North American Isotretinoin Information and Survey Line	Richard Miller, Ph.D. Professor and Associate Chair of Obstetrics and Gynecology
	Questions to OTIS from the Committee	
3:00	Break	
3:15	Risk Management Options for Pregnancy Prevention	Kathleen Uhl, M.D. Pregnancy Labeling Team, FDA
	Selecting Risk Management Tools: Considerations and Experience	Anne Trontell, M.D., M.P. H. Deputy Director Office of Drug Safety, FDA
	Questions to Speakers from the Committee	

5:30 **Adjourn**

Food and Drug Administration
Center for Drug Evaluation and Research

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

Hilton, 620 Perry Parkway, Gaithersburg, Maryland

Agenda **February 27, 2004**

8:00	Call to Order and Opening Remarks	Peter Gross, M.D. Chair, DSaRM
	Conflict of Interest Statement	Kimberly Topper, M.S. Executive Secretary, DODAC

Effectiveness of the isotretinoin risk management program for the prevention of fetal exposure to Accutane and its generic equivalents and consideration of whether changes to this isotretinoin risk management program would be appropriate

8:30	Open Public Hearing	
9:40	Break	
10:00	Introduction of Questions	Paul Seligman, M.D., M.P.H. Director, Office of Pharmacoepidemiology and Statistical Science, FDA
10:20	Committee Discussion	
12:00	Lunch	
1:00	Committee Discussion	
5:00	Adjourn	