

**FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH (CDER)**

Drug Safety and Risk Management Advisory Committee (DSaRM)

**Holiday Inn Gaithersburg
Two Montgomery Village Avenue
Gaithersburg, Maryland
February 9 & 10, 2006**

AGENDA

DAY ONE-FEBRUARY 9th

8:00 a.m.	Call to Order and Introductions	Peter Gross, M.D., Chair Drug Safety and Risk Management Advisory Committee (DSaRM)
	Conflict of Interest Statement	Victoria Ferretti-Aceto, Pharm.D. Executive Secretary, DSaRM
8:15 a.m.	Opening Remarks	Dr. Gerald Dal Pan, M.D., M.H.S., Director, Office of Drug Safety
8:30 a.m.	Overview of Attention Deficit Hyperactivity Disorder (ADHD) and its Pharmacotherapy	Andrew Mosholder, M.D., M.P.H.
9:00 a.m.	Studying Cardiovascular Risk with Drug Treatments of ADHD	Kate Gelperin, M.D., M.P.H.
9:30 a.m.	ADHD Drugs and Cardiovascular Outcomes: Feasibility Study Results	David Graham, M.D., M.P.H.
10:00 a.m.	Break	
10:15 a.m.	Challenges of Studying Cardiovascular Outcomes in ADHD	Elizabeth Andrews, M.P.H., Ph.D.
10:45 a.m.	Question and Answers	
11:30 a.m.	Lunch	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Break	
2:15 p.m.	Introduction of Questions	Gerald Dal Pan, M.D., M.H.S.
2:30 p.m.	Committee Discussion of Questions	
5:00 p.m.	Adjourn	

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AGENDA

DAY TWO-FEBRUARY 10th

8:00 a.m.	Call to Order and Introductions	Peter Gross, M.D., Chair Drug Safety and Risk Management Advisory Committee (DSaRM)
	Conflict of Interest Statement	Victoria Ferretti-Aceto, Pharm.D. Executive Secretary, DSaRM
8:15 a.m.	Open Public Hearing	
9:15 a.m.	Office of Drug Safety Updates	Gerald Dal Pan, M.D., M.H.S.
9:35 a.m.	Question and Answers	
9:45 a.m.	New Drug Safety Initiatives and the Drug Safety Oversight Board	Susan Cummins, M.D., M.P.H.
10:15 a.m.	Question and Answers	
10:30 a.m.	Break	
10:45 a.m.	An Update on NSAID Labeling and Data Review	Sharon Hertz, M.D.
11:15 a.m.	Question and Answers	
11:30 a.m.	Introduction to Isotretinoin Risk Management Program	Jill Lindstrom, M.D., F.A.A.D.
11:35 a.m.	iPLEDGE Isotretinoin Pregnancy Risk Management Program	Susan Ackermann Shiff, PhD Global Head, Risk Management, Hoffmann-La Roche Inc. Christine Mundkur Senior VP, Quality and Regulatory Counsel, Barr Laboratories, Inc. James Shamp Director, Covance, Inc.
12:15 a.m.	Question and Answers	
12:45 p.m.	Adjourn	