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

Drug Safety and Risk Management Advisory Committee (DSaRM)

Holiday Inn
8777 Georgia Avenue
Silver Spring, Maryland
May 18 & 19, 2005

AGENDA

This the first in a series of meetings related to issues in drug safety and the FDA. This two-day meeting will explore issues related to FDA's risk assessment program for marketed drugs. There are a number of methods that FDA uses in risk assessment of marketed drugs, including review and analysis of spontaneous reports of adverse events, drug use data, healthcare administrative data, epidemiologic and observational studies, clinical trials, and active surveillance systems. Considerations will include the advantages and disadvantages of the current system for safety signal detection, and proposals for short-term and long-term ways to improve the current system.

DAY 1 WEDNESDAY MAY 18, 2005

8:00	Call to Order and Introductions	Peter Gross, M.D., Chair, DSaRM
	Conflict of Interest Statement	Shalini Jain, PA-C Executive Secretary, DSaRM
8:15	Opening Remarks	Paul Seligman, M.D. Director Office of Pharmacoepidemiology and Statistical Science (OPaSS)
8:30	Using the FDA's Adverse Event Reporting System (AERS) in Postmarketing Surveillance	Joyce Weaver, Pharm.D., B.C.P.S. Safety Evaluator, Division of Drug Risk Evaluation (DDRE), Office of Drug Safety (ODS)
9:00	Epidemiologic Analysis of Spontaneous Adverse Reports	Mary Willy, Ph.D. Epidemiology Team Leader, DDRE, ODS
9:15	Using FDA's AERS in Postmarketing Surveillance for Medication Errors	Carol Holquist, R.Ph Director Division of Medication Errors and Technical Support (DMETS), ODS
9:30	Available Types of National Drug Use Data	Judy Staffa, Ph.D., R.Ph. Epidemiology Team Leader, Division of Surveillance, Research and Communication Support (DSRCS), ODS
9:45	Question and Answer Period	

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AGENDA (cont.)

DAY 1 WEDNESDAY MAY 18, 2005 (cont.)

10:00	Break	
10:15	Issues in the Practical Application of Data Mining Techniques to Pharmacovigilance	A. Lawrence Gould, Ph.D. Senior Director, Scientific Staff, Biostatistics and Research Decision Sciences Merck Research Laboratories
10:35	Data Mining AERS, FDA's (Spontaneous) Adverse Event Reporting System	Carolyn McCloskey, M.D., M.P.H. Epidemiologist DDRE, ODS
10:45	Question and Answer Period	
11:00	Open Public Hearing	
12:00	Lunch	
1:00	Active Surveillance for Drug Safety Signals: Past, Present and Future	Mary Willy, Ph.D. Epidemiology Team Leader DDRE, ODS
1:30	*NEISS:CADES Active Surveillance System	Aaron Mendelsohn, Ph.D., M.P.H. Epidemiologist DSRCS, ODS
1:45	Active Surveillance Using Longitudinal Data: A Pilot Project	David Graham, M.D., M.P.H. Medical Officer, OPaSS
2:05	Question and Answer Period	
2:30	Break	
2:45	Questions to the Committee	
5:00	Adjourn	

*NEISS:CADES-National Electronic Injury Surveillance System: Cooperative Adverse Drug Events Surveillance System

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DAY 2 THURSDAY MAY 19, 2005

8:00	Call to Order and Introductions	Peter Gross, M.D., Chair, DSaRM
	Conflict of Interest Statement	Shalini Jain, PA-C, Executive Secretary, DSaRM
8:15	Opening remarks	Paul Seligman, M.D., M.P.H., Director, OPaSS
8:20	Overview of Drug Safety Challenges	Gerald DalPan, M.D., M.H.S., Director, DSRCS, ODA ODS
8:50	Pregnancy Exposure Registries	Kathleen Uhl, M.D. Pregnancy & Lactation Team, Office of New Drugs
9:10	Postmarketing Studies from OND Perspective	Julie Beitz, M.D. Deputy Director, Office of Drug Evaluation III
9:40	Post marketing Studies from the Industry Perspective	Gretchen S. Dieck, Ph.D., Vice President, Management Strategy, Worldwide Development, Pfizer, Inc.
10:10	Population-Based Epidemiologic Safety Studies – Overview Challenges	David Graham, M.D., M.P.H., Medical Officer, ODS
10:40	Question and Answer Period	
11:00	Break	
11:10	Open Public Hearing	
11:40	Lunch	
12:40	Questions to the Committee	
5:00	Adjourn	