FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31, the Great Room,
White Oak Conference Center (Room 1503), Silver Spring, MD
December 12, 2012

AGENDA

The Food and Drug Administration Amendments Act of 2007 requires FDA to bring, at least annually, one or more drugs with Risk Evaluation and Mitigation Strategies (REMS) with Elements to Assure Safe Use (ETASU) before CDER's Drug Safety and Risk Management Advisory Committee (DSaRM). The Agency plans to present information on the risk management of teratogens, some of which have REMS with ETASU.

On December 12, 2012, the committee will meet to discuss the various strategies used by the Agency to define and address teratogenic risk, including requiring REMS with ETASU. The discussion will include an evaluation of the different strategies and the decision framework for selecting risk management strategies for teratogens. The committee will discuss whether the risk management strategies, including REMS with ETASU, assure safe use, are not unduly burdensome to patient access to the drug, and to the extent practicable, minimize the burden to the health care delivery system.

8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	**Almut Winterstein, PhD** Acting Chairperson, Drug Safety and Risk Management Advisory Committee (DSaRM)
	Conflict of Interest Statement	**Kristina A. Toliver, PharmD** Designated Federal Officer, DSaRM
8:10 a.m.	Opening Remarks	**Claudia Manzo, PharmD** Director, Division of Risk Management (DRISK) Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER), FDA
	FDA Presentations	
8:15 a.m.	Evidence for Teratogenic Risk: Assessment of Animal and Human Data	**Melissa S. Tassinari, PhD DABT** Acting Team Leader – Maternal Health Team Pediatric and Maternal Health Staff (PMHS) Office of New Drugs (OND), CDER, FDA
8:35 a.m.	Retrospective review of FDA's teratogenicity risk management approaches	**Mwango Kashoki, MD, MPH** Associate Director for Safety Team Leader - Safety Policy and Research Team OND, CDER, FDA
8:55 a.m.	Teratogenic drugs: Evaluation of the effectiveness of risk management strategies	**Doris Auth, PharmD** Team Leader– REMS Assessment Team DRISK/OSE, CDER, FDA
9:15 a.m.	Framework for Decisions to Manage Teratogenic Risk	**Amarilys Vega, MD, MPH** Risk Management Analyst DRISK/OSE, CDER, FDA
9:35 a.m.	Example of a Teratogenic Risk Management Decision	**Mary Ross Southworth, PharmD** Deputy Director for Safety Division of Cardiovascular and Renal Products OND, CDER, FDA

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AGENDA (cont.)

9:55 a.m.	Clarifying Questions for the Presenters	
10:15 a.m.	**BREAK**	
10:30 a.m.	**Industry Perspective:** Management of the teratogenic potential of drug products	**John Freeman, MSc, BSc (Hons), LLB (Hons)** Corporate Vice President Global Drug Safety & Risk Management, Celgene Corporation
11:00 a.m.	Clarifying Questions for the Presenter	
	Special Presentations:	
11:15 a.m.	*Prescriber perspective*: Clinical management of non-pregnant females of reproductive potential, who require treatment with teratogenic drug(s)	**Beth Choby, MD (Guest Speaker)** Associate Professor Department of Family Medicine University of Tennessee Health Sciences Center
11:30 a.m.	*Prescriber perspective*: Clinical management of pregnant females requiring treatment with teratogenic drug(s)	**Katherine Wisner, MD, MS (Speaker and Discussant)** Asher Professor of Psychiatry and Obstetrics and Gynecology Director, Asher Center for Research and Treatment of Depressive Disorders Northwestern University Feinberg School of Medicine
11:45 a.m.	*Patient perspective*: Female patients of reproductive potential experience with teratogenic drug(s)	**Kate Ryan, MPA (Guest Speaker)** Senior Program Coordinator National Women's Health Network
12:00 p.m.	Clarifying Questions for the Speakers	
12:15 p.m.	**LUNCH**	
1:15 p.m.	Open Public Hearing	
1:45 p.m.	Questions to the Committee/ Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/ Committee Discussion (cont)	
5:45 p.m.	**ADJOURNMENT**	