

# FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

*Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Dermatologic and Ophthalmic Drugs Advisory Committee (DODAC)*

FDA White Oak Campus, Building 31, the Great Room,  
White Oak Conference Center (Room 1503), Silver Spring, MD  
December 1, 2011

## DRAFT AGENDA

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*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 its Drug Safety and Risk Management Advisory Committee (DSaRM). On December 1, 2011, the DSaRM and the Dermatologic and Ophthalmic Drugs Advisory Committees will meet in joint session to discuss REMS-related topics. During the morning session, the committees will discuss the REMS program for isotretinoin, also known as iPLEDGE, as an example of a REMS that has ETASU.*

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8:00 a.m.	Call to Order and Opening Remarks Introduction of Committee	<b>Lewis Nelson, M.D.</b> Chairperson, Drug Safety and Risk Management Advisory Committee (DSaRM)
	Conflict of Interest Statement	<b>Kristina A. Toliver, Pharm.D.</b> Designated Federal Officer, DSaRM
8:10 a.m.	Opening Remarks	<b>Claudia Karwoski, Pharm.D</b> Director Division of Risk Management (DRISK)
	<b><u>FDA Presentation</u></b>	
8:15 a.m.	History of Isotretinoin Risk Management	<b>Jill Lindstrom, M.D.</b> Medical Officer, Team Leader Division of Dermatology and Dental Products (DDDP)
	<b><u>Industry Presentation</u></b>	
8:25 a.m.	iPLEDGE Program Overview	<b>James Shamp</b> Director, Risk Management Programs United BioSource Corp.
	<b><u>FDA Presentation</u></b>	
9:00 a.m.	iPLEDGE: Effects on Burden and Access	<b>Marta Wosinska, Ph.D.</b> Director for Analysis Staff Office of Policy and Analysis
	<b><u>Industry Presentation</u></b>	
9:15 a.m.	iPLEDGE Pregnancy Data	<b>Eric Davis, M.D.</b> Director, Medical Services Mylan Pharmaceuticals

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### **FDA Presentation**

- 9:25 a.m. FDA Perspective on iPLEDGE REMS Assessment findings **Kathryn O'Connell, M.D., Ph.D.**  
Medical Officer, DRISK
- 9:40 a.m. Open Public Hearing, iPLEDGE
- 10:10 a.m. **BREAK**
- 10:25 a.m. Clarifying Questions to the Presenters
- 11:00 a.m. Questions to the DSaRM and DODAC  
and DSaRM and DODAC Discussion-  
iPLEDGE Program
- 12:00 p.m. **LUNCH**

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1:00 p.m.	Call to Order Introduction of Committee	<b>Lewis Nelson, M.D.</b> Chairperson, DSaRM
	Conflict of Interest Statement	<b>Kristina A. Toliver, Pharm.D.</b> Designated Federal Officer, DSaRM
	<b><u>FDA Presentations</u></b>	
1:05 p.m.	Implementing REMS in Healthcare Delivery Systems	<b>Reema Jain, Pharm.D., M.P.H.</b> Risk Management Analyst, DRISK
1:20 p.m.	Defining and Measuring Effects on Access and Burden	<b>Marta Wosinska, Ph.D.</b> Director for Analysis Staff Office of Policy and Analysis
1:35 p.m.	REMS in Modern Pharmacy System	<b>Adam Kroetsch, MSPPM</b> Operations Research Analyst Office of Policy and Analysis
1:50 p.m.	Clarifying Questions to the Presenters	
2:05 p.m.	<b>BREAK</b>	
2:20 p.m.	Open Public Hearing, REMS with ETASU	
2:50 p.m.	Questions to the DSaRM and DODAC and DSaRM and DODAC Discussion- REMS with ETASU	
4:30 p.m.	<b>ADJOURNMENT</b>	