FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Drug Safety and Risk Management Advisory Committee (DSaRM) and the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
May 3-4, 2016

DRAFT AGENDA

The committees will discuss results from assessments of the extended-release and long-acting (ER/LA) Opioid Analgesics REMS. The Agency will seek the committees' comments as to whether this REMS with ETASU assures safe use, is not unduly burdensome to patient access to the drugs, and to the extent practicable, minimizes the burden to the healthcare delivery system.

Day 1: Tuesday, May 3, 2016

8:00 a.m.	Call to Order and Introduction of Committees	**Almut Winterstein, MD** Chairperson, DSaRM
8:15 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
8:20 a.m.	FDA Introductory Remarks	**Janet Woodcock, MD** Director CDER, FDA
8:35 a.m.	**FDA PRESENTATIONS**	
	Background and History of ER/LA Opioid REMS	**Terry Toigo, MBA, RPh** Associate Director for Drug Safety Operations CDER, FDA
	REMS Authority, Overview of ER/LA REMS and ER/LA REMS Assessment Plan	**Cynthia LaCivita, PharmD** Director, Division of Risk Management (DRISK) Office of Surveillance and Epidemiology (OSE) CDER, FDA
9:10 a.m.	**NIH PRESENTATION**	
	Additional Federal and State Efforts	**Wilson Compton, MD, MPE** Deputy Director National Institute on Drug Abuse (NIDA) National Institutes of Health (NIH)
9:30 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	

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DRAFT AGENDA (cont.)

10:15 a.m.	**INDUSTRY PRESENTATIONS**	**REMS Programs Companies (RPC)**
	Introduction/REMS Design	**Paul M. Coplan, ScD, MBA** Head of Medical Affairs Strategic Research Purdue Pharma Adjunct Assistant Professor of Epidemiology, University of Pennsylvania School of Medicine
	REMS Continuing Education Progress and Results	**Marsha Stanton, PhD, MS, RN** Executive Director of Medical Affairs Pernix Therapeutics
	Perspective of a Pain Medicine Physician and Educator	**Charles E. Argoff, MD** Professor of Neurology, Albany Medical College Director of the Comprehensive Pain Center Albany Medical Center
	REMS Assessment Metrics Progress and Results	**M. Soledad Cepeda, MD, PhD** Director of Epidemiology Janssen Research & Development
	Surveillance Data of the Public Health Impact	**Richard C. Dart, MD, PhD** Executive Director, RADARS System Director, Rocky Mountain Poison and Drug Center Professor of Emergency Medicine, University of Colorado School of Medicine
	Lessons Learned and Recommendations	**Laura Wallace, MPH** Director, Risk Management & Epidemiology Purdue Pharma
	Conclusions	**Paul M. Coplan, ScD, MBA**
11:45 a.m.	Clarifying Questions	
12:15 p.m.	**LUNCH**	
1:15 p.m.	**FDA PRESENTATIONS**	
	Introduction to FDA Presentations and Training Metrics	**Igor Cerny, PharmD** REMS Assessment Analyst DRISK, OSE, CDER, FDA

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DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

	Prescriber and Patient Surveys	**Shelly Harris, MPH** REMS Assessment Analyst DRISK, OSE, CDER, FDA **Catherine (Ya-Hui) Hsueh, PhD** Mathematical Statistician Division of Biometrics VII (DBV-II) Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Surveillance and Utilization	**Jana McAninch, MD, MPH, MS** Medical Officer Division of Epidemiology II (DEPI-II) OSE, CDER, FDA
	Summary and Recommendations	**Igor Cerny, PharmD**
2:30 p.m.	Clarifying Questions	
3:00 p.m.	**BREAK**	
3:15 p.m.	**ORGANIZATIONS' PRESENTATIONS**	
	Report From the Frontlines	**Cynthia Kear** Senior VP, California Academy of Family Physicians Project Lead, Collaboration for REMS Education (CO*RE)
	ER/LA Opioid REMS Education: A Clinical Perspective	**Kevin Zacharoff, MD** Faculty, SUNY Stony Brook School of Medicine Medical Director, PainEDU.org
	Perspectives of the Conjoint Committee on CE: Medicine, Nursing, Dentistry, Pharmacy, Physician Assistants and Nurse Practitioners	**Norman Kahn, MD** Executive Vice President and CEO Council of Medical Specialty Societies (CMSS) Convener, Conjoint Committee for Continuting Education
4:00 p.m.	Clarifying Questions	
5:00 p.m.	**ADJOURNMENT**	

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DRAFT AGENDA (cont.)

Day 2: Wednesday, May 4, 2016

8:00 a.m.	Call to Order and Introduction of the Committees	**Almut Winterstein, MD** Chairperson, DSaRM
8:15 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, DSARM
8:20 a.m.	FDA Introductory Remarks	**Cynthia LaCivita, PharmD**
8:25 a.m.	**ORGANIZATIONS' PRESENTATIONS**	
	A Coordinated Regulatory and Educational Approach to the Public Health Crisis of Chronic Pain and Addiction	**Joanna G. Katzman, MD, MSPH** University of New Mexico Health Sciences Center
	Promoting Best Practices and the Public Health with Accredited CE	**Graham McMahon, MD** President and CEO Accreditation Council for Continuing Medical Education (ACCME)
8:55 a.m.	Clarifying Questions	
9:10 a.m.	**FDA PRESENTATION**	
	Considerations for Modification of a REMS	**Doris Auth, PharmD** REMS Assessment Team LeaderDRISK, OSE, CDER, FDA
9:25 a.m.	Clarifying Questions	
9:40 a.m.	**BREAK**	
10:00 a.m.	**OPEN PUBLIC HEARING**	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Charge to the Committee	**Doris Auth, PharmD**
1:15 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	

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DRAFT AGENDA (cont.)

5:00 p.m. **ADJOURNMENT**