

**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

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	
	Development of the 2012 Extended-Release and Long-Acting (ER/LA) Opioid Analgesic REMS	Terry Toigo, MBA, RPh Associate Director for Drug Safety Operations CDER, FDA
	Risk Evaluation and Mitigation Strategy (REMS) Authority and Extended-Release and Long-Acting (ER/LA) REMS	Cynthia LaCivita, PharmD Director, Division of Risk Management (DRISK) Office of Surveillance and Epidemiology (OSE) CDER, FDA
9:10 a.m.	NIH PRESENTATION	
	Responding to the Opioid Morbidity and Mortality	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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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 Reviews of the Extended-Release and Long-Acting (ER/LA) Opioid Analgesic REMS 36-month Assessment	Igor Cerny, PharmD REMS Assessment Analyst DRISK, OSE, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Extended-Release and Long-Acting
(ER/LA) Opioid Analgesics REMS
36 month Assessment: Review of Prescriber
and Patient Surveys

Shelly Harris, MPH
REMS Assessment Analyst
Division of Risk Management (DRISK)
OSE, CDER, FDA

Catherine (Ya-Hui) Hsueh, PhD
Mathematical Statistician
Division of Biometrics VII (DB-VII)
Office of Biostatistics (OB)
Office of Translational Sciences (OTS), CDER, FDA

Extended-Release and Long Acting
(ER/LA) Opioid Analgesic REMS
36 month Assessment: Review of
Epidemiologic and Drug Utilization
Surveillance Studies

Jana McAninch, MD, MPH, MS
Medical Officer
Division of Epidemiology II (DEPI-II)
OSE, CDER, FDA

Extended-Release and Long-Acting
(ER/LA) Opioid Analgesic REMS 36 month
Assessment: FDA Conclusions and
Considerations for Next Steps

Igor Cerny, PharmD

2:30 p.m. Clarifying Questions

3:00 p.m. **BREAK**

3:15 p.m. **ORGANIZATIONS' PRESENTATIONS**

CO*RE: 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

Educating Clinicians in ER/LA Opioid
REMS: Experiences of the Conjoint
Committee on Continuing Education

Norman Kahn, MD
Executive Vice President and CEO
Council of Medical Specialty Societies (CMSS)
Convener, Conjoint Committee for Continuing
Education

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AGENDA (cont.)

4:00 p.m. Clarifying Questions

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

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 Modifications to the
ER/LA Opioid Analgesic REMS

Doris Auth, PharmD
REMS Assessment Team Leader
Division of Risk Management (DRISK)
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

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AGENDA (cont.)

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