

# ***Industry Meeting to Discuss Opioid Analgesic REMS***

## **AGENDA**

**January 25, 2017**

**9:30 am – 11:30 am CSU Room 2047W**

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### **FOOD AND DRUG ADMINISTRATION**

#### **Center for Drug Evaluation and Research (CDER)**

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9:30 am - 9:35 am	Welcome	Douglas C. Throckmorton, MD Deputy Director for Regulatory Programs CDER
9:35 am – 9:40 am	Introductions	Terry Toigo, RPh MBA Associate Director for Drug Safety Operations CDER
9:40 am – 9:50 am	Development of the 2012 ER/LA Opioid Analgesic REMS	Terry Toigo, RPh, MBA Associate Director for Drug Safety Operations CDER
9:50 am – 10:00 am	Advice from Joint DSaRM and AADPAC Advisory Committees May 3-4, 2016	Doris Auth, Pharm.D. Associate Director (Acting) Division of Risk Management Office of Medication Error Prevention and Risk Management, CDER
10:00 am – 10:10 am	FDA Plan: Opioid Analgesic Education	Sharon Hertz, MD Director, Division of Anesthesia, Analgesia and Addiction Products Office of New Drugs, CDER
10:10 am – 10:25 am	Development of Shared System REMS	Elaine Lippmann, J.D. Senior Regulatory Counsel Office of Regulatory Policy, CDER
10:25 am – 10:40 am	ER/LA Opioid Analgesics REMS Overview – REMS Program Companies (RPC) Presentation.	Greg Wedin Associate Director, Pharmacovigilance & Medical Information, Upsher-Smith Laboratories  Nathan Kopper, Pharm.D. REMS Manager, Mallinckrodt
10:40 am – 11:30 am	Questions and Comments from Industry	FDA/Industry Panel