# 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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<th>Time</th>
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<th>Speaker(s)</th>
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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                                                           |