

# FDA Regulatory Processes and Standards for Review and Approval of Opioid Analgesics: An Educational Primer and Conversation

February 10, 2009

1:00-5:00 p.m.

Hilton Washington DC/Rockville

1750 Rockville Pike

Rockville, Maryland 20852

## PRELIMINARY AGENDA

### Meeting Goals:

- To discuss FDA regulatory processes and standards for review and approval of opioid analgesics
- To discuss FDA's limitations in authority for regulating opioid drug products and balancing the needs of diverse groups
- To provide an opportunity for FDA to hear perspectives regarding abuse prevention and pain management from various constituencies and other government agency staff

### 1:00 p.m. Welcome

*Speaker: Terry Toigo, R.Ph., M.B.A., Director, Office of Special Health Issues (OSHI)  
Office of the Commissioner (OC)*

### 1:15 p.m. Regulatory Issues in Reviewing and Approving Opioid Analgesics

FDA regulatory processes and standards for the review and approval of opioid analgesics. Includes an overview of the roles and responsibilities of other government agencies in the review and approval process.

*Speaker: Bob A. Rappaport, M.D., Director, Division of Analgesics, Anesthetics, and Rheumatology Products, Center for Drug Evaluation and Research (CDER)*

### 1:45 p.m. FDA's Involvement in Preventing Opioid Abuse

FDA's role in review and assessment of abuse potential. Current FDA actions to prevent opioid abuse, including collaboration with other government agencies, professional groups, and industry; risk management and monitoring.

*Speaker: Michael Klein, Ph. D., Director, Controlled Substance Staff, CDER*

### 2:00 p.m. Risk Management Strategies for Opioids and Methods of Surveillance

*Speaker: Gerald Dal Pan, M.D., Director, Office of Surveillance and Epidemiology, CDER*

### 2:15 p.m. Q&A

### 2:30 p.m. BREAK

### 2:40 p.m. Roles of Drug Enforcement Administration, FDA, and National Association of State Controlled Substance Authorities – Panel

Relationship between FDA and enforcement authorities, monitoring the criminal justice system; the role of Drug Enforcement Administration (DEA) and compliance with the law and regulations, inspections, and investigations; the states' role from the National Association of State Controlled Substance Authorities.

*Speakers: Mark Caverly, Chief, Liaison and Policy Section, Office of Diversion, DEA  
Jason Woo, Associate Director for Scientific and Medical Affairs, Office of Compliance, CDER  
Karen Tannert, President, National Association of State Controlled Substance Authorities*

### 3:15 p.m. Q&A

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**3: 30p.m. Other Government Agency Activities:  
How the National Institute on Drug Abuse's (NIDA) Initiatives Promote Understanding of  
Prescription Opiates**

*Speaker: Betty Tai, Ph.D., Director, Center for the Clinical Trials Network, NIDA*

**Substance Abuse and Mental Health Services Administration (SAMHSA) Initiatives to  
Educate Prescribers and Consumers and Treatment Resources**

*Speaker: Nick Reuter, MPH, Senior Public Health Analyst, SAMHSA*

**4:00 p.m. Q&A**

**4:15 p.m. Open Discussion/Closing Remarks/Next Steps**

*Moderator: Doug Throckmorton, M.D., Deputy Director, CDER*

**5:45 ADJOURN**