

Food and Drug Administration (FDA)
Center for Drug Evaluation and Research (CDER)
Drug Safety and Risk Management Advisory Committee (DSaRM)
FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)
White Oak Conference Center, Silver Spring, MD
January 24-25, 2013

AGENDA

The committee will discuss the public health benefits and risks, including the potential for abuse, of drugs containing hydrocodone either combined with other analgesics or as an antitussive. The Department of Health and Human Services received a request from the Drug Enforcement Administration for a scientific and medical evaluation and scheduling recommendation for these products in response to continued reports of misuse, abuse and addiction related to these products. The committee will also discuss the impact of rescheduling these hydrocodone products from Schedule III to Schedule II.

Day 1: January 24, 2013:

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| 8:00 a.m. | Call to Order Introduction of Committee | James Woods, PhD Acting Chairperson, DSaRM |
| | Conflict of Interest Statement | Kristina A. Toliver, PharmD Designated Federal Officer, DSaRM |
| 8:10 a.m. | Opening Remarks | Michael Klein, PhD Director, Controlled Substance Staff (CSS) Center for Drug Evaluation and Research (CDER), FDA |
| | <u>FDA Response to the Petition:</u> | |
| 8:25 a.m. | Controlled Substances Act Scheduling Process | Julie Finegan, JD Associate Chief Counsel for Drugs Office of Chief Counsel Office of the Commissioner, FDA |
| 8:35 a.m. | Overview of DEA's Request for Re-scheduling Hydrocodone Combination Products from Schedule III to Schedule II of the Controlled Substances Act (CSA) | Silvia N. Calderon, PhD Team Leader, Pharmacology Review Team CSS, CDER, FDA |

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AGENDA (cont.)

FDA Presentations continued –
Office of Surveillance and
Epidemiology (OSE):

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| 8:55 a.m. | Drug Utilization Patterns for Combination Hydrocodone-Containing Products and Selected Opioid Analgesics Years 2007-2011 | Rajdeep Gill, PharmD Drug Utilization Data Analyst, Division of Epidemiology (DEPI)-II Office of Surveillance and Epidemiology (OSE), CDER, FDA |
| 9:20 a.m. | OSE Epidemiologic Analysis of Misuse/Abuse of Hydrocodone-containing Analgesics | Catherine Dormitzer, PhD, MPH Epidemiologist, DEPI-II OSE, CDER, FDA |
| 9:45 a.m. | Committee Questions to Presenters | |
| | <u>Presentation by Speaker:</u> | |
| 10:00 a.m. | Abuse Potential of Hydrocodone in Human Studies | Sharon L. Walsh, PhD (Speaker) Professor of Behavioral Science, Psychiatry and Director of the Center on Drug and Alcohol Research University of Kentucky |
| 10:20 a.m. | Committee Questions to Presenter | |
| 10:30 a.m. | BREAK | |
| | <u>Presentation by Drug Enforcement Administration (DEA):</u> | |
| 10:45 a.m. | FDA Drug Safety and Risk Management Advisory Committee Concerning Hydrocodone Combination Products | Joseph T. Rannazzisi Deputy Assistant Administrator Office of Diversion Control U.S. Drug Enforcement Administration |
| 11:10 a.m. | Committee Questions to Presenter | |
| 11:30 a.m. | LUNCH | |

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AGENDA (cont.)

Presentation by Industry:

- 12:30 p.m. Public Health Benefits and Risks of Hydrocodone Combination Analgesic Products **David Gaugh, RPh**
Senior Vice President Sciences and Regulatory GPhA
Affiliation/Generic Pharmaceutical Association (GPhA)
- 1:30 p.m. Committee Questions to Presenter

Presentation by Speakers:

- 1:45 p.m. A Pain Physician's View of Impact of Schedule Change of Hydrocodone/APAP **Edward Michna, MD, JD (Speaker)**
Director, Pain Trials Center
Brigham and Women's Hospital
Boston, Massachusetts
Assistant Professor, Harvard Medical School
- 2:05 p.m. Prescription Drug Monitoring Plans: Evaluation of Effectiveness **Eric Lavonas, MD (Guest Speaker)**
Associate Director
Rocky Mountain Poison and Drug Center
Denver Health and Hospital Authority
Associate Professor, Department of Emergency Medicine
University of Colorado School of Medicine
- 2:25 p.m. The Role of Education in Safe and Effective Pain Management **Kevin L. Zacharoff, MD, FACPE, FACIP, FAAP (Guest Speaker)**
Vice President of Medical Affairs
Inflexxion, Inc.
- 2:45 p.m. Committee Questions to Presenters
- 3:30 p.m. **BREAK**

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AGENDA (cont.)

Presentations by Professional
Associations:

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| 3:45 p.m. | Rescheduling Hydrocodone: Patient and Public Health Considerations | American Academy of Pain Medicine (AAPM) Lynn Webster, MD President-Elect, AAPM Medical Director, CRI Lifetree Salt Lake City, Utah |
| 4:05 p.m. | FDA Advisory Committee Hearing on Potential Rescheduling of Hydrocodone: Pharmacist and Pharmacy Issues to Consider | American Pharmacists Association (APhA) Steve Simenson, BPharm, FAPhA, DPNAP APhA President 2013-2014 President and Managing Partner, Goodrich Pharmacy, Inc., Anoka, Minnesota American Pharmacists Association (APhA) Marcie Bough, PharmD Senior Director, Government Affairs APhA |
| 4:25 p.m. | Hydrocodone Combination Analgesic Products: Clinical Impact of a Schedule Change | American Dental Association & American Association of Oral and Maxillofacial Surgeons Frederick A. Curro, DMD, PhD Director, PEARL Practice Based Research Network Director Regulatory Affairs, Bluestone Center for Clinical Research Clinical Professor, Dept. of Oral Radiology, Pathology & Medicine New York University College of Dentistry |
| 4:45 p.m. | Drug Safety and Risk Management Committee (DSaRM) | American Optometric Association Jimmy D. Bartlett, OD Chairman and CEO, Pharmakon Consulting Group |
| 5:05 p.m. | Health Benefits/Risks of Drugs Containing Hydrocodone | American Society of Addiction Medicine Phillip Bradley Hall, MD WV Medical Professionals Health Pro Executive Medical Director Bridgeport, West Virginia |
| 5:25 p.m. | Committee Questions to Presenters | |
| 6:00 p.m. | ADJOURNMENT | |

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AGENDA (cont.)

Day 2- January 25, 2013:

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| 8:00 a.m. | Call to Order Introduction of Committee | James Woods, PhD Acting Chairperson, DSaRM |
| | Conflict of Interest Statement | Kristina A. Toliver, PharmD Designated Federal Officer, DSaRM |
| | Summary of Day One | James Woods, PhD Acting Chairperson, DSaRM |
| 8:15 a.m. | Open Public Hearing | |
| 9:45 a.m. | BREAK | |
| 10:00 a.m. | Open Public Hearing (cont.) | |
| 11:30 a.m. | LUNCH | |
| 12:30 p.m. | Presentation of Questions to the Committee | James Woods, PhD Acting Chairperson, DSaRM |
| 12:45 p.m. | Discussion/Vote by Committee | |
| 2:30 p.m. | BREAK | |
| 2:45 p.m. | Discussion/Vote by Committee (cont.) | |
| 5:00 p.m. | ADJOURNMENT | |