

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

December 7, 2012

AGENDA

The committee will discuss the risks and benefits of new drug application (NDA) 202880, by Zogenix Inc., for hydrocodone bitartrate extended-release capsules (proposed trade name Zohydro ER), an opioid analgesic medication for the management of moderate to severe chronic pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. This formulation of hydrocodone bitartrate extended-release capsules represents the first single-entity (i.e., containing no other active pharmaceutical ingredients, such as acetaminophen or ibuprofen) hydrocodone-containing drug product. It will be formulated in dose strengths up to 50 mg, and administered twice daily (i.e., every 12 hours). The committee will be asked to determine whether the benefit-risk assessment of this product favors its approval for marketing.

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| 8:00 a.m. | Call to Order and Introduction of Committee | Randall P. Flick, MD, MPH Chairperson, AADPAC |
| 8:10 a.m. | Conflict of Interest Statement | Philip Bautista, PharmD Designated Federal Officer, AADPAC |
| 8:15 a.m. | FDA Introductory Remarks | Bob Rappaport, MD Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA |
| 8:30 a.m. | SPONSOR PRESENTATIONS | Zogenix, Inc. |
| | Introduction | Stephen J. Farr, PhD President and Chief Operating Officer Zogenix, Inc. |
| | Medical Need for Zohydro ER | Richard L. Rauck, MD Pain Fellowship Doctor, Wake Forest University President, Carolinas Pain Institute President-elect, World Institute of Pain |
| | Zohydro ER Clinical Program Overview | James Breitmeyer, MD, PhD Chief Medical Officer Zogenix, Inc. |
| | Zohydro ER Risk Evaluation and Mitigation Strategies (REMS) and Safe Use Initiatives | Stephen J. Farr, PhD |
| | Benefits Risk Conclusions | James Breitmeyer, MD, PhD |

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AGENDA (cont.)

- 10:00 a.m. Clarifying Questions to the Sponsor
- 10:15 a.m. **BREAK**
- 10:30 a.m. **FDA PRESENTATION**
- Outpatient Drug Utilization Patterns For Selected Opioid Analgesics in the U.S., Years 2007-2011 **Rajdeep Gill, PharmD**
Drug Utilization Data Analyst
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology (OPE)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA
- 10:50 a.m. **SPEAKER PRESENTATION**
- Abuse Potential of Hydrocodone in Human Studies **Sharon L. Walsh, PhD**
Director
Center on Drug Abuse and Alcohol Research
University of Kentucky College of Medicine
- 11:10 a.m. **FDA PRESENTATIONS**
- Misuse/Abuse of Hydrocodone and Oxycodone Products by Composition and Formulation: Findings from the Drug Abuse Warning Network (DAWN) **Catherine Dormitzer, PhD, MPH**
Epidemiologist
DEPI-II, OPE, OSE, CDER, FDA
- Extended-Release/Long-Acting Opioid Analgesics REMS: An Overview **Robert A. Levin, MD**
Medical Officer
DAAAP, ODE-II, OND, CDER, FDA
- 11:45 a.m. Clarifying Questions to the FDA and Speaker
- 12:00 p.m. **LUNCH**
- 1:00 p.m. Open Public Hearing Session
- 2:30 p.m. Charge to the Committee **Bob Rappaport, MD**
- 2:35 p.m. Questions to the Committee/Committee Discussion
- 3:30 p.m. **BREAK**

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AGENDA (cont.)

3:45 p.m. Questions to the Committee/Committee
Discussion

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