

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
September 11, 2015

AGENDA

The committees will discuss new drug application (NDA) 208090, oxycodone extended-release capsules for oral use, submitted by Collegium Pharmaceuticals, proposed for the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. This product has been formulated with the intent to provide abuse-deterrent properties. Pharmacokinetic data demonstrate that, in order to deliver the intended amount of oxycodone, the drug product must be taken with food. The committees will be asked to discuss the potential safety risks and the potential effects on efficacy associated with the extent of the food effect, and potential fluctuations in oxycodone levels that may occur if the product is not taken consistently with the same amount of food. In addition, the committees will be asked to review and discuss whether the data characterizing the abuse-deterrent properties support the likelihood that this drug product will have a meaningful effect on abuse and whether potential benefits to the public from abuse-deterrent properties outweigh potential risks to patients from the effect of food. The committees will be asked to vote on whether this product should be approved for marketing in the United States.

9:30 a.m.	Call to Order and Introduction of Committee	Almut Winterstein, RPh, PhD, FISPE Chairperson, DSaRM
9:35 a.m.	Conflict of Interest Statement	Stephanie L. Begansky, PharmD Designated Federal Officer, AADPAC
9:40 a.m.	Opening Remarks	Sharon Hertz, MD Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	APPLICANT PRESENTATIONS	Collegium Pharmaceutical, Inc.
	Introduction	Michael Heffernan, RPh Founder and Chief Executive Officer Collegium Pharmaceutical, Inc.
	Medical Need	Bill McCarberg, MD Elizabeth Hospice and Neighborhood Healthcare

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Abuse-Deterrence Studies **Alison Fleming, PhD**
Vice President, Product Development
Collegium Pharmaceutical, Inc.

Efficacy and Safety **Ernest Kopecky, PhD, MBA**
Vice President, Clinical Development
Collegium Pharmaceutical, Inc.

Clinical Pharmacology and Food Effect **Nicholas Fleischer, RPh, PhD**
Vice President
The Weinberg Group, Inc.

Risk Management **Michael Heffernan, RPh**

Benefit-Risk Profile **Nathaniel Katz, MD, MS**
President
Analgesics Solutions

10:45 a.m. Clarifying Questions

11:00 a.m. **BREAK**

11:15 a.m. **FDA PRESENTATIONS**

Food Effect with Xtampza ER **Srikanth C. Nallani, PhD**
Clinical Pharmacology Reviewer
Division of Clinical Pharmacology II
Office of Clinical Pharmacology
Office of Translational Sciences, CDER, FDA

Results of the Oral Human Abuse Liability
Study **James M. Tolliver, PhD**
Pharmacology Reviewer
Controlled Substance Staff, CDER, FDA

Clinical Implications of Xtampza ER's Food
Effect **Ellen W. Fields, MD, MPH**
Clinical Team Leader
DAAAP, ODE II, OND, CDER, FDA

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AGENDA (cont.)

SPEAKER PRESENTATION

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| 11:45 p.m. | Patient-Centered Rx Communication:
Strategies to Mitigate/Minimize Risk | Michael S. Wolf, PhD, MPH
Professor, Medicine and Learning Sciences
Associate Chair, Department of Medicine
Associate Division Chief - Research
General Internal Medicine & Geriatrics
Feinberg School of Medicine
Northwestern University
Chicago, Illinois |
| 12:15 p.m. | Clarifying Questions | |
| 12:30 p.m. | LUNCH | |
| 1:30 p.m. | Open Public Hearing | |
| 2:30 p.m. | Questions to the Committee/Committee
Discussion | |
| 3:30 p.m. | BREAK | |
| 3:45 p.m. | Questions to the Committee/Committee
Discussion (cont.) | |
| 5:00 p.m. | ADJOURNMENT | |