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
May 5, 2016

AGENDA

The committee will discuss new drug application (NDA) 208653, benzhydrocodone/acetaminophen, submitted by KemPharm, Inc., with the proposed indication of short-term (up to 14 days) management of acute pain. The product has been formulated with the intent to provide abuse-deterrent properties. Benzhydrocodone is a hydrocodone prodrug, which according to the Applicant, is rapidly converted into hydrocodone by enzymes in the gastrointestinal tract. The active drugs in this fixed-dose combination are hydrocodone and acetaminophen. The Applicant has submitted data to support abuse-deterrent properties for this product. The committees will be asked to discuss whether the Applicant has demonstrated abuse-deterrent properties for their product that would support labeling, and whether the nasal route of abuse is relevant for combination products made up of hydrocodone and acetaminophen

---

9:15 a.m.	Call to Order and Introduction of Committee	**Raeford E. Brown, Jr., MD, FAAP** Acting Chairperson, AADPAC
9:20 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
9:25 a.m.	FDA Introductory Remarks	**Ellen Fields, MD** Deputy Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
9:30 a.m.	**APPLICANT PRESENTATIONS**	**KemPharm, Inc.**
	Introduction	**Travis Mickle, PhD** Chief Executive Officer KemPharm, Inc.
	Clinical Perspective	**Jeffrey Gudin, MD** Director of Pain Management and Palliative Care Englewood Hospital and Medical Center Clinical Instructor, Anesthesiology Icahn School of Medicine at Mt. Sinai
	Development Overview	**Travis Mickle, PhD**
	Tampering Studies	**Travis Mickle, PhD**

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)
May 5, 2016

AGENDA (cont.)

	APPLICANT PRESENTATIONS (CONT.)	
	Clinical Abuse-Deterrence Studies	**Lynn Webster, MD** Vice President, Scientific Affairs PRA Health Sciences
	Post-Marketing Surveillance Future Studies	**Travis Mickle, PhD**
	Benefit-Risk Profile	**Jeffrey Gudin, MD**
10:30 a.m.	Clarifying Questions	
10:45 a.m.	**BREAK**	
11:00 a.m.	**FDA PRESENTATIONS**	
	In Vitro Abuse Deterrent Studies	**Benjamin D. Stevens, PhD, MPH** Office of New Drug Products (ONDP) Office of Pharmaceutical Quality (OPQ), CDER, FDA
	Results of Human Abuse Potential Studies	**James M. Tolliver, PhD** Controlled Substance Staff, CDER, FDA
	Drug Utilization Patterns for Combination Hydrocodone/Acetaminophen and Other Selected Opioid Analgesics, Years 2011-2015	**Rajdeep Gill, PharmD** Division of Epidemiology II (DEPI II) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Is Snorting a Relevant Route of Abuse for Hydrocodone Combination Products?	**Jana McAninch, MD, MPH, MS** DEPI II, OPE, OSE, CDER, FDA
12:15 a.m.	Clarifying Questions	
12:30 p.m.	**LUNCH**	
1:30 p.m.	Open Public Hearing	
2:30 p.m.	Charge to the Committee	**Sharon Hertz, MD** Director DAAAP, ODEII, OND, CDER, FDA

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)
May 5, 2016

AGENDA (cont.)

2:35 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**