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
June 7, 2016

AGENDA

The committees will be asked to discuss new drug application (NDA) 207975, hydrocodone bitartrate extended-release tablets, submitted by Teva Pharmaceuticals, Inc., with the proposed indication of management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is an extended-release formulation intended to have abuse-deterrent properties based on the physiochemical properties of the formulation. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

9:30 a.m.	Call to Order and Introduction of Committee	**Raeford E. Brown, Jr., MD, FAAP** Acting Chairperson, AADPAC
9:35 a.m.	Conflict of Interest Statement	**Stephanie L. Begansky, PharmD** Designated Federal Officer, AADPAC
9:40 a.m.	FDA Introductory Remarks	**Ellen Fields, MD, MPH** Deputy Director Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE-II) Office of New Drugs (OND), CDER, FDA
9:45 a.m.	**APPLICANT PRESENTATIONS**	**Teva Branded Pharmaceutical Products R&D, Inc.**
	Introduction	**Douglas C. Harnish, PhD** Senior Director, Pain and Migraine Regulatory Affairs Teva Pharmaceuticals
	Chronic Pain and Opioid Abuse	**Charles Argoff, MD** Professor of Neurology Director, Comprehensive Pain Center Albany Medical Center, New York
	Clinical Efficacy and Safety	**Richard Malamut, MD** Senior Vice President, Global Clinical Development Teva Pharmaceuticals
	Abuse Deterrence Studies (Category 1)	**Derek Moe, PhD** Vice President, Drug Delivery Technology Teva Pharmaceuticals

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Abuse Deterrence Studies (Category 2 and 3)	**Lynn Webster, MD** Vice President, Scientific Affairs PRA Health Sciences Salt Lake City, Utah
	Summary & Benefit-Risk	**Richard Malamut, MD**
10:45 a.m.	Clarifying Questions	
11:00 a.m.	**BREAK**	
11:15 a.m.	**FDA PRESENTATIONS**	
	Drug Utilization Patterns for Hydrocodone ER and Other ER/LA Opioid Analgesics 2011-2015	**Joann H. Lee, PharmD** Drug Utilization Data Analyst Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Vantrela ER (hydrocodone bitartrate) Extended-Release Tablets Labeling Section 9: Drug Abuse	**Robert A. Levin, MD** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
11:45 a.m.	Clarifying Questions	
12:00 p.m.	**LUNCH**	
1:00 p.m.	Open Public Hearing	
2:00 p.m.	Charge to the Committee	**Sharon Hertz, MD** Director DAAAP, ODE-II, OND, CDER, FDA
2:05 p.m.	Questions to the Committee/Committee Discussion	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion (cont.)	
4:00 p.m.	**ADJOURNMENT**	