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
February 14, 2018

AGENDA

The committees will be asked to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Charleston Laboratories, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term management of acute pain severe enough to require an opioid analgesic while preventing and reducing opioid-induced nausea and vomiting. The committees will also be asked to discuss the abuse potential of this non-abuse-deterrent product and whether it should be approved.

8:00 a.m.	Call to Order and Introduction of Committee	**Mary Ellen McCann, MD, MPH** Acting Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, AADPAC
8:10 a.m.	FDA 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
8:15 a.m.	**APPLICANT PRESENTATIONS**	**Charleston Laboratories, Inc.**
	Introduction: Today's Purpose	**Thomas Smith, MD** Chief Medical Officer Charleston Laboratories, Inc. Jupiter, Florida
	Need for New Approach to Treat Acute Pain While Preventing and Reducing OINV	**Tong Joo (TJ) Gan, MD, MBA, MHS, FRCA** Professor and Chairman Department of Anesthesiology Stony Brook University School of Medicine Stony Brook, New York
	Abuse Potential & Human Abuse Liability	**Sandra D. Comer, PhD** Professor of Neurobiology College of Physicians and Surgeons Columbia University New York, New York

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

	Clinical Development and Efficacy	**Bernard P. Schachtel, MD** Chief Scientific Officer Charleston Laboratories, Inc. Jupiter, Florida
	Clinical Safety, Responsible Use & Benefit-Risk Assessment	**Thomas Smith, MD**
9:00 a.m.	Clarifying Questions	
9:10 a.m.	**FDA PRESENTATIONS**	
	Clinical Considerations in the Evaluation of the Safety and Effectiveness of Hydexor	**Timothy Jiang, MD, PhD** Clinical Reviewer DAAAP, ODE-II, OND, CDER, FDA
	Utilization Patterns for Combination Hydrocodone-Acetaminophen, Selected Opioid Analgesics, and Promethazine-Containing Products	**LCDR Jennie Z. Wong, PharmD** Drug Utilization Analyst Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Postmarketing Data on Misuse and Abuse of Hydrocodone and Promethazine	**Jana McAninch, MD, MPH, MS** Senior Medical Epidemiologist Prescription Drug Abuse Team DEPI-II, OPE, OSE, CDER, FDA
	Summary of FDA Findings	**Ellen Fields, MD, MPH** Deputy Director DAAAP, ODE-II, OND, CDER, FDA
9:55 a.m.	Clarifying Questions	
10:05 a.m.	**BREAK**	
10:15 a.m.	**OPEN PUBLIC HEARING**	

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11:15 a.m.	Charge to the Committee	**Sharon Hertz, MD**
11:20 a.m.	Questions to the Committee/ Committee Discussion	
12:30 p.m.	**ADJOURNMENT**	