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
August 4, 2016

DRAFT AGENDA

The committees will discuss new drug application (NDA) 208603, morphine sulfate extended-release tablets, submitted by Egalet U.S., Inc., with the proposed indication of the management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. It has been formulated with the intent to provide abuse-deterrent properties. 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** 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**	**Egalet U.S., Inc.**
	Introduction	**Robert Radie** President and Chief Executive Officer Egalet Corporation
	Public Health Need	**Richard C. Dart, MD, PhD** Director Denver Health & Hospital Authority
	Abuse-Deterrent Studies	**Jeffrey M. Dayno, MD** Chief Medical Officer Egalet Corporation
	Clinical Relevance	**Nathaniel Katz, MD, MS** President, Analgesic Solutions Adjunct Assistant Professor of Anesthesia Tufts University School of Medicine
10:45 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

11:00 a.m.	**BREAK**	
11:15 a.m.	**FDA PRESENTATIONS**	
	Results of Oral Human Abuse Potential Study	**James M. Tolliver, PhD** Pharmacologist Controlled Substance Staff Office of Center Director CDER, FDA
	Drug Utilization Patterns for Morphine Sulfate Extended-Release 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
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	
3:15 p.m.	**BREAK**	
3:30 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:00 p.m.	**ADJOURNMENT**	