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)
College Park Marriott Hotel and Conference Center, General Vessey Ballroom
3501 University Blvd., Hyattsville, Maryland
May 22, 2018

DRAFT AGENDA

The committees will be asked to discuss new drug application (NDA) 209588, for buprenorphine sublingual spray, submitted by INSYS Development Company, Inc., for the treatment of moderate-to-severe acute pain where the use of an opioid analgesic is appropriate. The committees will also be asked to discuss whether this product should be approved.

8:00 a.m.	Call to Order and Introduction of Committee	**Almut Winterstein, RPh, PhD, FISPE** Chairperson, DSaRM
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**	**INSYS Development Company Inc.**
	Introduction	**Stephen Sherman, JD, MBA** Senior Vice President, Regulatory Affairs and Clinical Development, Insys Development Co.
	Medical Landscape and Unmet Need	**Joseph Pergolizzi, MD** Senior Partner and Director of Research Naples Anesthesia and Pain Associates, Florida Adjunct Assistant Professor Johns Hopkins University School of Medicine
	Development Rationale, Pharmacokinetics, Efficacy, and Safety	**Dean Mariano, DO** Senior Director of Clinical Development and Medical Affairs, Insys Development Co.
	Risk Management	**Stephen Sherman, JD, MBA**
	Benefit/Risk Assessment	**Joseph Pergolizzi, MD**
9:45 a.m.	Clarifying Questions	

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DRAFT AGENDA (cont.)

10:15 a.m.	**FDA PRESENTATIONS**	
	Clinical Overview	**Robert Levin, MD** Clinical Reviewer DAAAP, ODE-II, OND, CDER, FDA
	Drug Utilization Analysis and Assessment of Postmarket Abuse-Related Issues	**Cynthia Kornegay, PhD** Senior Epidemiologist Prescription Drug Abuse Team Division of Epidemiology II (DEPI-II) Office of Pharmacovigilance and Epidemiology (OPE) Office of Surveillance and Epidemiology (OSE) CDER, FDA
11:15 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**
2:05 p.m.	Questions to the Committee/ Committee Discussion	
4:30 p.m.	**ADJOURNMENT**	