

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

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
	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	
10:15 a.m.	BREAK	

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AGENDA (cont.)

10:30 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

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

11:30 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

3:00 p.m. **BREAK**

3:15 p.m. Questions to the Committee/
Committee Discussion

4:30 p.m. **ADJOURNMENT**