

**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  
October 5, 2016

**DRAFT AGENDA**

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*The committees will be asked to discuss naloxone products intended for use in the community, specifically the most appropriate dose or doses of naloxone to reverse the effects of life-threatening opioid overdose in all ages and the role of having multiple doses available in this setting. The committees will also be asked to discuss the criteria prescribers will use to select the most appropriate dose in advance of an opioid overdose event and the labeling to inform this decision, if multiple doses are available.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Raeford E. Brown Jr., MD, FAAP</b> Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	<b>Jennifer Shepherd, RPh</b> Acting Designated Federal Officer, AADPAC
8:10 a.m.	FDA Introductory Remarks	<b>Joshua Lloyd, MD</b> Clinical Team Leader 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.	<b>INDUSTRY PRESENTATIONS</b>	
	<b><u>Adapt Pharma Operations Limited</u></b> Community Use Naloxone Dose	<b>Seamus Mulligan, MS, BS</b> Chief Executive Officer Adapt Pharma Operations Limited
	<b><u>Amphastar Pharmaceuticals, Inc.</u></b> Introduction, Agenda & Presenters	<b>Jason Shandell, JD, MBA, Esq</b> President Amphastar Pharmaceuticals, Inc.
	Intranasal Off-Label Use of IMS Naloxone Injection (2mg/2mL) in Overdose Prevention Programs	<b>Tony Marrs, MPH</b> Vice President, Clinical Operations Amphastar Pharmaceuticals, Inc.
	Development of Intranasal Naloxone	<b>Robert Cormack, PhD</b> Senior Director, Regulatory Affairs Amphastar Pharmaceuticals, Inc.
	<b><u>Insys Therapeutics, Inc.</u></b> Innovative Delivery Systems for Naloxone	<b>Steve Sherman</b> Senior Vice President, Regulatory Affairs Insys Therapeutics, Inc.

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**DRAFT AGENDA (cont.)**

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**INDUSTRY PRESENTATIONS (CONT.)**

**kaléo, Inc.**

Naloxone HCl Products for Use in the  
Community Setting

**Eric S. Edwards, MD, PhD**

Vice President and Co-Founder  
kaléo, Inc.

9:35 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

Clinical and Regulatory Perspectives  
on Naloxone Products Intended for  
Use in the Community

**Jennifer Nadel, MD**

Medical Officer  
DAAAP, ODE-II, OND, CDER, FDA

The Current Approach to Relative  
Bioavailability Studies in Support of  
Approval of New Naloxone Products

**Yun Xu, PhD, MS**

Clinical Pharmacology Team Leader  
Division of Clinical Pharmacology 2  
Office of Clinical Pharmacology (OCP)  
Office of Translational Sciences (OTS), CDER, FDA

Drug utilization of naloxone

**Shekhar Mehta, PharmD, MS**

Drug Use Analyst  
Division of Epidemiology II (DEPI-II)  
Office of Pharmacovigilance and Epidemiology  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA

11:20 a.m. Clarifying Questions

11:35 a.m. **CENTERS FOR DISEASE CONTROL  
AND PREVENTION (CDC)  
PRESENTATION**

Trends in Multiple Naloxone  
Administrations among EMS  
Personnel

**Mark Faul, PhD, MA**

Senior Health Scientist  
Division of Unintentional Injury Prevention  
National Center for Injury Prevention and Control  
Centers for Disease Control and Prevention

12:00 p.m. Clarifying Questions

12:15 p.m. **LUNCH**

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1:15p.m.      **OPEN PUBLIC HEARING**

2:15 p.m.      Charge to the Committee      **Sharon Hertz, MD**  
Director  
DAAAP, ODE-II, OND, CDER, FDA

2:20 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**

DRAFT