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

AGENDA

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.

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

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AGENDA (cont.)

	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 Utilization 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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1:15 p.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**	