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)
Tommy Douglas Conference Center
10000 New Hampshire Ave, Silver Spring, Maryland
September 14, 2017

DRAFT AGENDA

The committees will discuss the supplemental new drug application (sNDA) 021306, for Butrans (buprenorphine) transdermal system submitted by Purdue Pharma LP, evaluating Butrans in pediatric patients ages 7 through 16 years. The committees will be asked to discuss the findings of the clinical study of Butrans conducted in pediatric patients, and whether they support additional labeling.

8:00 a.m.	Call to Order and Introduction of Committee	**Brian Bateman, MD, MSc** Acting Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	**Stephanie Begansky, 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**	**Purdue Pharma, L.P.**
	Introduction and Pediatric Study Context	**Craig Landau, MD** President & CEO
	Regulatory History Utilization of Opioids in Pediatric Patients	**Richard Fanelli, PhD** Head of Regulatory Affairs
	Pediatric Clinical Trial	**Stacy Baldridge, MSN, RN** Pediatric Lead
9:00 a.m.	Clarifying Questions	
9:10 a.m.	**FDA PRESENTATIONS**	
	Development of Opioids in Pediatric Patients: Conclusions from FDA's September 2016 Advisory Committee Meeting, and the Latest Agency Thinking on Studying Opioids in Children	**Ellen Fields, MD, MPH** Deputy Division Director DAAAP, ODE-II, OND, CDER, FDA

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)
September 14, 2017

DRAFT AGENDA (cont.)

FDA PRESENTATIONS (CON'T)

FDA Clinical Review of Study 3031 and Discussion	**Robert A. Levin, MD** Medical Officer DAAAP, ODE-II, OND, CDER, FDA
Pediatric Pharmacokinetic Assessment of Butrans in Study 3031	**Gopichand Gottipati, PhD** Pharmacometrics Reviewer Division of Pharmacometrics Office of Clinical Pharmacology Office of Translational Sciences, CDER, FDA

9:55 a.m. Clarifying Questions

10:05 a.m. **BREAK**

10:15 a.m. **OPEN PUBLIC HEARING**

11:15 a.m. Questions to the Committee/Committee Discussion

12:30 p.m. **ADJOURNMENT**