FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
October 12, 2018

AGENDA

The committee will be asked to discuss new drug application (NDA) 209128, sufentanil sublingual tablets, submitted by AcelRx Pharmaceuticals, Inc., for the management of moderate-to-severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adult patients in a medically supervised setting. The committee will also be asked to discuss risk-benefit considerations and whether this product should be approved.

8:00 a.m.	Call to Order and Introduction of Committee	**Kevin Zacharoff, MD, FACIP, FACPE, FAAP** Acting Chairperson, AADPAC
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
8:25 a.m.	**APPLICANT PRESENTATIONS**	**AcelRx Pharmaceuticals, Inc.**
	Introduction/Overview of DSUVIA	**Pamela Palmer, MD, PhD** Chief Medical Officer AcelRx Pharmaceuticals, Inc.
	Unmet Need	**James Miner, MD** Chief of Emergency Medicine Hennepin County Medical Center
	Clinical Pharmacology of Sublingual Sufentanil	**Dennis Fisher, MD** Founder *P Less Than* Pharmacometric Consulting Professor (Emeritus), Department of Anesthesia University of California, San Francisco
	Efficacy	**Pamela Palmer, MD, PhD**
	Safety	**Neil Singla, MD** Chief Scientific Officer Lotus Clinical Research, LLC
	Benefit/Risk Conclusion	**Pamela Palmer, MD, PhD**

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9:40 a.m.	Clarifying Questions	
10:00 a.m.	**BREAK**	
10:15 a.m.	**FDA PRESENTATIONS**	
	Introduction and Review of Clinical Safety and Efficacy	**Ning Hu, MD, MS** Clinical Reviewer DAAAP, ODE-II, OND, CDER, FDA
	Human Factors Evaluation	**Otto L. Townsend, PharmD** Team Leader Division of Medication Error Prevention and Analysis Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE) CDER, FDA
	Risk Evaluation and Mitigation Strategies (REMS) Considerations	**LaShaun Washington-Batts, PharmD** Reviewer Division of Risk Management OMEPRM, OSE, CDER, FDA
	Benefit/Risk Considerations	**Ning Hu, MD, MS**
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	
3:00 p.m.	**BREAK**	
3:15 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	