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

Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
***and the Drug Safety and Risk Management Advisory Committee (DSaRM*)**
February 15, 2022

DRAFT AGENDA

The committees will be asked to discuss new drug application (NDA) 213231 for tramadol hydrochloride injection, submitted by Avenue Therapeutics, Inc., for the management of moderate to moderately severe pain in adults in a medically supervised health care setting. The issues for the committees to discuss include the clinical relevance of tramadol hydrochloride injection, an opioid intended for management of acute pain in a medically supervised healthcare setting, when its onset of action is delayed, and its proposed dosing is a fixed-dosing regimen.

9:30 a.m.	Call to Order and Introduction of Committee	**Brian T. Bateman, MD, MSc** Chairperson, AADPAC
9:45 a.m.	Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Designated Federal Officer, AADPAC
9:50 a.m.	FDA Opening Remarks	**Rigoberto Roca, MD** Director Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience (ON) Office of New Drugs (OND), CDER, FDA
9:55 a.m.	**APPLICANT PRESENTATIONS**	**Avenue Therapeutics, Inc.**
	Introduction	**Lucy Lu, MD** President and CEO Avenue Therapeutics, Inc.
	Mechanism of Action and Intravenous (IV) Tramadol Experience in European Union	**Prof. Richard Langford, MD** Lead Consultant Pain Service, The London Clinic
	Pharmacokinetics, Clinical Efficacy, and Safety	**Lucy Lu, MD**
	Discussion of FDA Concerns	**Lucy Lu, MD**
	Epidemiology of Abuse of Tramadol	**Janetta Iwanicki, MD** Chief Scientific Officer Rocky Mountain Poison and Drug Safety
	Clinical Perspective from a U.S. Investigator	**Harold Minkowitz, MD** Adjunct Associate Professor Anesthesiology and Perioperative Medicine MD Anderson Cancer Center

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DRAFT AGENDA (cont.)

11:25 a.m.	Clarifying Questions for Applicant	
11:45 a.m.	**BREAK**	
11:55 a.m.	**FDA PRESENTATIONS**	
	Tramadol IV: A Multidisciplinary Review	**Lisa Wiltrout, MD** Medical Officer DAAP, ON, OND, CDER, FDA
	Abuse Potential Considerations for Tramadol IV Injection Under NDA 213231	**James M. Tolliver, PhD** Senior Pharmacologist Controlled Substance Staff, CDER, FDA
	Epidemiologic Data and Public Health Considerations in Evaluating Benefit-Risk of IV Tramadol	**Christina R. Greene, PhD** Senior Epidemiologist Division of Epidemiology II Office of Pharmacovigilance and Epidemiology Office of Surveillance and Epidemiology CDER, FDA
12:55 p.m.	Clarifying questions for FDA	
1:15 p.m.	**LUNCH**	
2:00 p.m.	**OPEN PUBLIC HEARING**	
3:00 p.m.	Charge to the Committee	**Rigoberto Roca, MD**
3:10 p.m.	Questions to the Committee/Committee Discussion	
4:00 p.m.	**BREAK**	
4:10 p.m.	Questions to the Committee/Committee Discussion (cont.)	
5:15 p.m.	**ADJOURNMENT**	