

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

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	Brian T. Bateman, MD, MSc Chairperson, AADPAC
9:35 a.m.	Introduction of Committee and Conflict of Interest Statement	Moon Hee V. Choi, PharmD Designated Federal Officer, AADPAC
9:45 a.m.	Statement on Formal Dispute Resolution Request	Moon Hee V. Choi, PharmD
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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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**