

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

**Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)**  
January 10, 2025

**AGENDA**

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*The Committee will discuss BLA 761393, condoliase injection submitted by Seikagaku Corp., for the proposed indication of the treatment of radicular leg pain associated with confirmed nerve root impingement caused by lumbar disc herniation in adults.*

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9:00 a.m.	Call to Order and Introduction of Committee	<b>Brian Bateman, MD, MSc</b> Chair, AADPAC
9:10 a.m.	Conflict of Interest Statement	<b>LaToya Bonner, PharmD, MBA</b> Acting Designated Federal Officer, AADPAC
9:15 a.m.	FDA Opening Remarks	<b>Tina Doshi, MD, MHS</b> Associate Director for Therapeutic Review Division of Anesthesiology, Addiction Medicine, and Pain Medicine (DAAP), Office of Neuroscience (ON), Office of New Drugs (OND), CDER, FDA
9:20 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Seikagaku Corporation</b>
	Introduction	<b>Jun Watanabe, RPh, EMBA, MSc</b> General Manager
	Unmet Need	<b>Ajay D. Wasan, MD, MSc</b> Professor; Vice Chair for Pain Medicine; Director, Chronic Pain Research Program; Director, Center for Innovation in Pain Care University of Pittsburgh School of Medicine
	Condoliase Efficacy	<b>Joe Stauffer, DO, MBA, FAPCR</b> Chief Medical Advisor
	Condoliase Safety	<b>Diane Martire, MD, MPH</b> Safety Advisor
	Disc-related Imaging Findings	<b>Thomas Fuerst, PhD</b> Radiology Advisor

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**APPLICANT PRESENTATIONS**  
**(cont.)**

Clinical Perspective

**Kee D Kim, MD**

Chief, Spinal Neurosurgery; Co-Director, Professor  
of Neurological Surgery  
University of California, Davis Spine Center

10:50 a.m. Clarifying Questions for Applicant

11:05 a.m. **BREAK**

11:15 a.m. **FDA PRESENTATIONS**

FDA Assessment of  
Condoliase

**Shaan Sudhakaran, MD**

Medical Officer  
DAAP, OND, ON, CDER, FDA

12:00 p.m. Clarifying Questions for FDA

12:15 p.m. Lunch Break

1:15 p.m. **OPEN PUBLIC HEARING**

2:15 p.m. Charge to the Committee

**Tina Doshi, MD, MHS**

DAAP/ON/OND/CDER/FDA

2:20 p.m. Questions to the Committee/Committee  
Discussion

**Tina Doshi, MD, MHS**

DAAP/ON/OND/CDER/FDA

3:30 p.m. **BREAK**

3:45 p.m. Questions to the Committee/Committee  
Discussion (cont.)

4:30 p.m. **ADJOURNMENT**