

**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)***

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)  
10903 New Hampshire Avenue, Silver Spring, Maryland  
January 15, 2020 (AM Session)

**DRAFT AGENDA**

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*The committees will be asked to discuss new drug application (NDA) 213426 for tramadol 44mg and celecoxib 56mg tablet, which contains a fixed dose combination of an opioid and an NSAID, submitted by Esteve Pharmaceuticals, S.A., for the management of acute pain in adults that is severe enough to require an opioid analgesic and for which alternative treatments are inadequate. The committees will also be asked to discuss the safety, and efficacy data as well as the overall risk-benefit profile of the product.*

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8:00 a.m.	Call to Order and Introduction of Committee	<b>Ronald S. Litman, DO, ML</b> Chairperson, AADPAC
8:05 a.m.	Conflict of Interest Statement	<b>Moon Hee V. Choi, PharmD</b> Designated Federal Officer, AADPAC
8:10 a.m.	FDA Opening Remarks	<b>Naomi Lowy, MD</b> Deputy Director (Acting) Division of Anesthesiology, Addiction Medicine and Pain Medicine (DAAP) Office of Neuroscience Office of New Drugs, CDER, FDA
8:15 a.m.	<b>APPLICANT PRESENTATIONS</b>	<b>Esteve Pharmaceuticals, S.A.</b>
	Introduction	<b>Mark Mayhew, PhD</b> Director, CTC Program Esteve Pharmaceuticals, S.A.
	Urgent Need in Opioid Analgesia	<b>Eugene R. Viscusi, MD</b> Professor of Anesthesiology Chief of Pain Medicine Director, Acute Pain Management Thomas Jefferson University Philadelphia, PA
	Phase I Clinical Pharmacology Phase 2 Dose-Finding Study	<b>Carlos R. Plata-Salaman, DSc, MD</b> Chief Scientific Officer and Chief Medical Officer Esteve Pharmaceuticals, S.A.

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**APPLICANT PRESENTATIONS (CONT.)**

Phase 3 Efficacy and Safety

**Neus Gascon, MD**  
Head of Medical Sciences  
Esteve Pharmaceuticals, S.A.

Benefit-Risk Assessment

**Oscar de Leon-Casasola, MD**  
Chief, Division of Pain Medicine  
Professor of Oncology  
Roswell Park Cancer Institute  
Professor of Anesthesiology and Medicine  
The Jacobs School of Medicine at The University  
of Buffalo

9:15 a.m. Clarifying Questions

9:30 a.m. **FDA PRESENTATION**

Review of Recent Data on Use,  
Misuse, and Abuse of Tramadol  
and Comparator Drugs

**Saranrat Wittayanukorn, PhD**  
Epidemiologist  
Division of Epidemiology II  
Office of Pharmacovigilance and Epidemiology  
Office of Surveillance and Epidemiology  
CDER, FDA

10:00 a.m. Clarifying Questions

10:15 a.m. **BREAK**

10:30 a.m. **OPEN PUBLIC HEARING**

11:00 a.m. Charge to the Committee

**Naomi Lowy, MD**

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

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