

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

***Joint Meeting of the Psychopharmacologic Drugs Advisory Committee (PDAC) 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
November 1, 2017

AGENDA

The committees will discuss new drug application (NDA) 210136, buprenorphine subcutaneous injection, submitted by Braeburn Pharmaceuticals, Inc., for the proposed indication of treatment of opioid dependence.

8:00 a.m.	Call to Order and Introduction of Committee	Raj Narendran, MD Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	Kalyani Bhatt, MS Designated Federal Officer, PDAC
8:10 a.m.	FDA Opening Remarks	Celia Winchell, MD Clinical Team Leader Division of Anesthesia, Analgesia, and Addiction Products (DAAAP) Office of Drug Evaluation II (ODE II) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	Braeburn Pharmaceuticals, Inc.
	Introduction	Susan Franks, MS SVP and Head of Regulatory Affairs Braeburn Pharmaceuticals, Inc.
	Unmet Need	Michelle Lofwall, MD, DFASAM Associate Professor, Behavioral Science and Psychiatry, Center for Drug and Alcohol Research, University of Kentucky
	Clinical Pharmacokinetics	Fredrik Tiberg, PhD President and CEO Head of Research and Development, Camurus AB
	Efficacy: Opioid Challenge Study	Sharon Walsh, PhD Director, Center of Drug and Alcohol Research University of Kentucky
	Efficacy and Safety: Phase 3 Studies	Sonnie Kim, PharmD Chief Scientific Officer Braeburn Pharmaceuticals, Inc.
	Clinical Perspective	Michael Frost, MD, FACP, FASAM President/Medical Director The Frost Medical Group, LLC

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AGENDA (cont.)

9:45 a.m. Clarifying Questions

10:00 a.m. **BREAK**

10:15 a.m. **FDA PRESENTATIONS**

Clinical Overview

Gioia Guerrieri, DO

Clinical Reviewer

DAAAP, ODE II, OND, CDER, FDA

Blockade Study: Analyses and Issues

Qianyu Dang, PhD

Lead Statistician

Division of Biostatistics VI, Office of Biostatistics

(OB), Office of Translational Sciences (OTS)

CDER, FDA

Blockade Study: Pharmacokinetic-
Pharmacodynamic Analyses of Drug
Liking

Michael Bewernitz, PhD

Pharmacometrics Reviewer

Division of Pharmacometrics

Office of Clinical Pharmacology

OTS, CDER, FDA

Clinical and Statistical Review

James Travis, PhD

Statistics Reviewer

Division of Biostatistics II, OB, OTS, CDER, FDA

Gioia Guerrieri, DO

Proposed Risk Evaluation and Mitigation
Strategies (REMS) for CAM2038

Somya Dunn, MD

Commander, United States Public Health Service

RISK Management Analyst

Division of Risk Management

Office of Surveillance and Epidemiology

CDER, FDA

11:40 a.m. Clarifying Questions

12:00 p.m. **LUNCH**

1:00 p.m. **OPEN PUBLIC HEARING**

2:00 p.m. Charge to Committee

Sharon Hertz, MD

Director

DAAAP, ODEII, OND, CDER, FDA

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AGENDA (cont.)

- 2:10 p.m. Questions to the Committee/Committee Discussion
- 3:15 p.m. **BREAK**
- 3:30 p.m. Questions to the Committee/Committee Discussion (cont.)
- 5:00 p.m. **ADJOURNMENT**