

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

Psychopharmacologic Drugs Advisory Committee (PDAC) Meeting

FDA White Oak Campus, 10903 New Hampshire Avenue Building 31 Conference Center
The Great Room (Rm. 1503), Silver Spring, Maryland
January 12, 2016

AGENDA

The committee will discuss new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Braeburn Pharmaceuticals, Inc., on behalf of Titan Pharmaceuticals for the proposed indication of maintenance treatment of opioid dependence.

8:00 a.m.	Call to Order and Introduction of Committee	Judith M. Kramer, MD Acting Chairperson, PDAC
8:05 a.m.	Conflict of Interest Statement	Jennifer Shepherd, RPh Acting 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 (ODEII) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	APPLICANT PRESENTATIONS	Braeburn Pharmaceuticals, Inc.
	Introduction	Behshad Sheldon President & Chief Executive Officer Braeburn Pharmaceuticals
	Public Health Need	Frank Young, MD, PhD Executive Vice President, Regulatory and Medical Braeburn Pharmaceuticals
	Medical Need	Michelle Lofwall, MD Associate Professor, Depts of Behavioral Science & Psychiatry Center on Drug and Alcohol Research University of Kentucky College of Medicine
	Efficacy	Sonnie Kim, PharmD Vice President, Clinical Development and Medical Affairs Braeburn Pharmaceuticals

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AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Training Program & Safety	Steven Chavoustie, MD, FACOG Principal Investigator Segal Institute for Clinical Research Volunteer Assistant Professor, University of Miami Miller School of Medicine
Risk Management	Behshad Sheldon
Benefit/Risk	Michael Frost, MD, FACP, FASAM Medical Director, Eagleville Hospital President, Frost Medical Group
9:45 a.m.	Clarifying Questions to Applicant
10:00 a.m.	BREAK
10:10 a.m.	FDA PRESENTATIONS
Efficacy and Safety of Probuphine for the Maintenance Treatment of Opioid Dependence in Clinically Stable Patients	Rachel Skeete, MD, MHS Clinical Reviewer DAAAP, ODEII, OND, CDER, FDA James Travis, PhD Statistics Reviewer Division of Biostatistics II, Office of Biostatistics, Office of Translational Sciences, CDER, FDA
11:25 a.m.	Clarifying Questions to FDA
11:40 a.m.	LUNCH
12:40 p.m.	OPEN PUBLIC HEARING
2:10 p.m.	BREAK
2:20 p.m.	CHARGE TO THE COMMITTEE Sharon Hertz, MD Director DAAAP, ODEII, OND, CDER, FDA
2:25 p.m.	Questions to the Committee/Committee Discussion
5:00 p.m.	ADJOURNMENT