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

DRAFT 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** Acing 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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DRAFT 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**	
	Safety and Efficacy 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
2:25 p.m.	Questions to the Committee/Committee Discussion	
5:00 p.m.	**ADJOURNMENT**	