**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

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

**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)***
November 1, 2017

**DRAFT AGENDA (cont.)**

| | | |
|---|---|---|
| 9:45 a.m. | Clarifying Questions | |
| 10:00 a.m. | **BREAK** | |
| 10:15 a.m. | **FDA PRESENTATIONS** | |
| | Clinical Overview | **Gioia Guerrieri, DO**<br>Clinical Reviewer<br>DAAAP, ODE II, OND, CDER, FDA |
| | Blockade Study: Analyses and Issues | **Wei Liu, PhD**<br>Statistics Reviewer<br>Division of Biostatistics VI, Office of Biostatistics (OB), Office of Translational Sciences (OTS)<br>CDER, FDA |
| | Blockade Study: Pharmacokinetic-Pharmacodynamic Analyses of Drug Liking | **Michael Bewernitz, PhD**<br>Pharmacometrics Reviewer<br>Division of Pharmacometrics<br>Office of Clinical Pharmacology<br>OTS, CDER, FDA |
| | Clinical and Statistical Review | **James Travis, PhD**<br>Statistics Reviewer<br>Division of Biostatistics II, OB, OTS, CDER, FDA |
| | | **Gioia Guerrieri, DO** |
| | Proposed Risk Evaluation and Mitigation Strategies (REMS) for CAM2038 | **Somya Dunn, MD**<br>RISK Management Analyst<br>Division of Risk Management<br>Office of Surveillance and Epidemiology<br>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**<br>Director<br>DAAAP, ODEII, OND, CDER, FDA |

**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)***
November 1, 2017

**DRAFT 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**