The committees will discuss efficacy, safety and risk-benefit profile of new drug application (NDA) 210417, buprenorphine and samidorphan sublingual tablets, submitted by Alkermes, Inc., for adjunctive treatment of major depressive disorder.

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, BS, MS
Designated Federal Officer, PDAC

8:10 a.m. FDA Opening Remarks
Mitchell Mathis, MD
Director
Division of Psychiatry Products (DPP)
Office of Drug Evaluation I (ODE I)
Office of New Drugs (OND), CDER, FDA

8:15 a.m. APPLICANT PRESENTATIONS
Alkermes, Inc.

Introduction
Lisa von Moltke, MD
Senior Vice President, Clinical Development
Alkermes, Inc.

The Unmet Need in MDD, and Challenges in MDD Clinical Trials
George Papakostas, MD
Harvard Medical School
Massachusetts General Hospital

Clinical Efficacy
Jerald Schindler, DrPH
Vice President, Biostatistics
Alkermes, Inc.

Clinical Safety, and Risk Mitigation Strategies
Gary Bloomgren, MD
Vice President, Drug Safety and Pharmacovigilance
Alkermes, Inc.

Clinical Perspective and Benefit-Risk Profile
Sanjay Mathew, MD
Baylor College of Medicine

Conclusion
Lisa von Moltke, MD
9:45 a.m. Clarifying Questions to Applicant

10:15 a.m. BREAK

10:30 a.m. **FDA PRESENTATIONS**

**Regulatory History**

**Tiffany Farchione, MD**  
Deputy Director  
DPP, ODE I, OND, CDER, FDA

**Clinical Efficacy and Safety Overview**

**Semhar Ogbagaber, PhD**  
Statistician  
Division of Biometrics I  
Office of Biostatistics  
Office of Translational Sciences, CDER, FDA

**Abuse Potential of Buprenorphine/Samidorphan (BUP/SAM)**

**Edward Hawkins, PhD**  
Pharmacologist  
Controlled Substance Staff  
Office of the Center Director, CDER, FDA

**FDA Review of the Epidemiologic and Surveillance Data**

**Celeste Mallama, PhD, MPH**  
Epidemiologist  
Division of Epidemiology II  
Office of Surveillance and Epidemiology (OSE)  
CDER, FDA

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**UNIVERSITY OF WASHINGTON MEDICAL SCHOOL DEPARTMENT OF PSYCHIATRY & BEHAVIORAL SCIENCES PRESENTATION**

Depression Effects On Long-Term Prescription Opioid Use, Abuse and Addiction

**Mark Sullivan, MD, PhD**  
Professor, Psychiatry and Behavioral Sciences  
University of Washington Medical Center

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**FDA PRESENTATIONS (cont.)**

**Risk Management for Buprenorphine/Samidorphan**

**Somya Dunn, MD**  
Commander, United States Public Health Service  
Risk Management Analyst  
Division of Risk Management, OSE, CDER, FDA
AGENDA (cont.)

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<thead>
<tr>
<th>Time</th>
<th>Activity</th>
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<tbody>
<tr>
<td>12:00 p.m.</td>
<td>Clarifying Questions to FDA and Dr. Sullivan</td>
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<td>12:15 p.m.</td>
<td>LUNCH</td>
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<td>1:15 p.m.</td>
<td>OPEN PUBLIC HEARING</td>
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<td>2:15 p.m.</td>
<td>Charge to Committee                                   Mitchell Mathis, MD</td>
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<td>2:25 p.m.</td>
<td>Questions to the Committee/Committee Discussion</td>
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<td>3:20 p.m.</td>
<td>BREAK</td>
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<td>3:30 p.m.</td>
<td>Questions to the Committee/Committee Discussion (cont.)</td>
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<td>5:00 p.m.</td>
<td>ADJOURNMENT</td>
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