AGENDA

The committee will be asked to discuss new drug application (NDA) 209128, sufentanil sublingual tablets, submitted by AcelRx Pharmaceuticals, Inc., for the management of moderate-to-severe acute pain severe enough to require an opioid analgesic and for which alternative treatments are inadequate, in adult patients in a medically supervised setting. The committee will also be asked to discuss risk-benefit considerations and whether this product should be approved.

8:00 a.m.  Call to Order and Introduction of Committee

Kevin Zacharoff, MD, FACIP, FACPE, FAAP
Acting Chairperson, AADPAC

8:05 a.m.  Conflict of Interest Statement

Moon Hee V. Choi, PharmD
Designated Federal Officer, AADPAC

8:10 a.m.  FDA Opening Remarks

Sharon Hertz, MD
Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP)
Office of Drug Evaluation II (ODE-II)
Office of New Drugs (OND), CDER, FDA

8:25 a.m.  APPLICANT PRESENTATIONS

AcelRx Pharmaceuticals, Inc.

Introduction/Overview of DSUVIA
Pamela Palmer, MD, PhD
Chief Medical Officer
AcelRx Pharmaceuticals, Inc.

Unmet Need
James Miner, MD
Chief of Emergency Medicine
Hennepin County Medical Center

Clinical Pharmacology of Sublingual Sufentanil
Dennis Fisher, MD
Founder
P Less Than Pharmacometric Consulting
Professor (Emeritus), Department of Anesthesia
University of California, San Francisco

Efficacy
Pamela Palmer, MD, PhD

Safety
Neil Singla, MD
Chief Scientific Officer
Lotus Clinical Research, LLC

Benefit/Risk Conclusion
Pamela Palmer, MD, PhD
AGENDA

9:40 a.m.  Clarifying Questions

10:00 a.m.  BREAK

10:15 a.m.  FDA PRESENTATIONS

Introduction and Review of Clinical Safety and Efficacy  Ning Hu, MD, MS
Clinical Reviewer
DAAAP, ODE-II, OND, CDER, FDA

Human Factors Evaluation  Otto L. Townsend, PharmD
Team Leader
Division of Medication Error Prevention and Analysis
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
CDER, FDA

Risk Evaluation and Mitigation Strategies (REMS) Considerations  LaShaun Washington-Batts, PharmD
Reviewer
Division of Risk Management
OMEPRM, OSE, CDER, FDA

Benefit/Risk Considerations  Ning Hu, MD, MS

11:15 a.m.  Clarifying Questions

12:00 p.m.  LUNCH

1:00 p.m.  OPEN PUBLIC HEARING

2:00 p.m.  Charge to the Committee  Sharon Hertz, MD

2:05 p.m.  Questions to the Committee/Committee Discussion

3:00 p.m.  BREAK

3:15 p.m.  Questions to the Committee/Committee Discussion

5:00 p.m.  ADJOURNMENT