AGENDA

The committees will be asked to discuss new drug application (NDA) 207975, hydrocodone bitartrate extended-release tablets, submitted by Teva Pharmaceuticals, Inc., with the proposed indication of management of pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. The product is an extended-release formulation intended to have abuse-deterrent properties based on the physiochemical properties of the formulation. The committees will be asked to discuss whether the data submitted by the Applicant are sufficient to support labeling of the product with the properties expected to deter abuse.

9:30 a.m. Call to Order and Introduction of Committee

Raeford E. Brown, Jr., MD, FAAP
Acting Chairperson, AADPAC

9:35 a.m. Conflict of Interest Statement

Stephanie L. Begansky, PharmD
Designated Federal Officer, AADPAC

9:40 a.m. FDA Introductory Remarks

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

9:45 a.m. APPLICANT PRESENTATIONS

Teva Branded Pharmaceutical Products R&D, Inc.

Introduction

Douglas C. Harnish, PhD
Senior Director, Pain and Migraine
Regulatory Affairs
Teva Pharmaceuticals

Chronic Pain and Opioid Abuse

Charles Argoft, MD
Professor of Neurology
Director, Comprehensive Pain Center
Albany Medical Center, New York

Clinical Efficacy and Safety

Richard Malamut, MD
Senior Vice President, Global Clinical Development
Teva Pharmaceuticals

Abuse Deterrence Studies
(Category 1)

Derek Moe, PhD
Vice President, Drug Delivery Technology
Teva Pharmaceuticals
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Joint Meeting of the Anesthetic and Analgesic Drug Products Advisory Committee (AADPAC)
and the Drug Safety and Risk Management Advisory Committee (DSaRM)
June 7, 2016

AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Abuse Deterrence Studies
(Category 2 and 3)         Lynn Webster, MD
                           Vice President, Scientific Affairs
                           PRA Health Sciences
                           Salt Lake City, Utah

Summary & Benefit-Risk          Richard Malamut, MD

10:45 a.m.  Clarifying Questions

11:00 a.m.  BREAK

11:15 a.m.  FDA PRESENTATIONS

Drug Utilization Patterns
for Hydrocodone ER and Other
ER/LA Opioid Analgesics
2011-2015         Joann H. Lee, PharmD
                           Drug Utilization Data Analyst
                           Division of Epidemiology II (DEPI-II)
                           Office of Pharmacovigilance and Epidemiology
                           Office of Surveillance and Epidemiology (OSE)
                           CDER, FDA

Vantrela ER (hydrocodone bitartrate)
Extended-Release Tablets Labeling
Section 9: Drug Abuse          Robert A. Levin, MD
                           Medical Officer
                           DAAAAP, ODE-II, OND, CDER, FDA

11:45 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
                           Director
                           DAAAAP, ODE-II, OND, CDER, FDA

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 (cont.)

4:00 p.m.  ADJOURNMENT

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