The committees will be asked to discuss new drug application (NDA) 209257, proposed tradename, HYDEXOR, a fixed-dose combination oral tablet, submitted by Charleston Laboratories, Inc., that contains hydrocodone, acetaminophen, and promethazine, for the short-term management of acute pain severe enough to require an opioid analgesic while preventing and reducing opioid-induced nausea and vomiting. The committees will also be asked to discuss the abuse potential of this non-abuse-deterrent product and whether it should be approved.

8:00 a.m. Call to Order and Introduction of Committee
Mary Ellen McCann, MD, MPH
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

8:15 a.m. APPLICANT PRESENTATIONS
Charleston Laboratories, Inc.

Introduction: Today’s Purpose
Thomas Smith, MD
Chief Medical Officer
Charleston Laboratories, Inc.
Jupiter, Florida

Need for New Approach to Treat Acute Pain While Preventing and Reducing OINV
Tong Joo (TJ) Gan, MD, MBA, MHS, FRCA
Professor and Chairman
Department of Anesthesiology
Stony Brook University School of Medicine
Stony Brook, New York

Abuse Potential & Human Abuse Liability
Sandra D. Comer, PhD
Professor of Neurobiology
College of Physicians and Surgeons
Columbia University
New York, New York
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)
February 14, 2018

DRAFT AGENDA (cont.)

APPLICANT PRESENTATIONS (CONT.)

Clinical Development and Efficacy
Bernard P. Schachtel, MD
Chief Scientific Officer
Charleston Laboratories, Inc.
Jupiter, Florida

Clinical Safety, Responsible Use & Benefit-Risk Assessment
Thomas Smith, MD

9:00 a.m. Clarifying Questions

9:10 a.m. FDA PRESENTATIONS

Clinical Overview
Timothy Jiang, MD
Clinical Reviewer
DAAAP, ODE-II, OND, CDER, FDA

Drug Utilization
Jennie Z. Wong
Drug Utilization Analyst
Division of Epidemiology II (DEPI-II)
Office of Pharmacovigilance and Epidemiology (OPE)
Office of Surveillance and Epidemiology (OSE) CDER, FDA

Division of Epidemiology
Jana McAninch, MD, MPH, MS
Senior Medical Epidemiologist
Prescription Drug Abuse Team
DEPI-II, OPE, OSE, CDER, FDA

Summary of FDA Findings
Joshua Lloyd, MD
Clinical Team Leader
DAAAP, ODE-II, OND, CDER, FDA

9:55 a.m. Clarifying Questions

10:05 a.m. BREAK

10:15 a.m. OPEN PUBLIC HEARING
11:15 a.m. Charge to the Committee

Sharon Hertz, MD

11:20 a.m. Questions to the Committee/Committee Discussion

12:30 p.m. ADJOURNMENT