AGENDA

The committee will discuss new drug application (NDA) 210365, cannabidiol oral solution, sponsored by GW Pharma, for the adjunctive treatment of seizures associated with Lennox-Gastaut syndrome or Dravet syndrome in patients 2 years of age and older.

8:00 a.m. Call to Order and Introduction of Committee
G. Caleb Alexander, MD, MS
Chairperson, PCNS

8:05 a.m. Conflict of Interest Statement
Moon Hee V. Choi, PharmD
Acting Designated Federal Officer, PCNS

8:10 a.m. FDA Opening Remarks
Billy Dunn, MD
Director
Division of Neurology Products (DNP)
Office of Drug Evaluation I (ODE-I)
Office of New Drugs (OND), CDER, FDA

8:15 a.m. APPLICANT PRESENTATIONS
GW Pharmaceuticals

Cannabidiol Oral Solution (CBD-OS) Introduction
Alice Mead
Head of US Public Policy & Public Affairs
GW Pharmaceuticals

Unmet Need in Patients with Lennox-Gastaut Syndrome (LGS) and Dravet Syndrome (DS)
Elizabeth Thiele, MD, PhD
Director, Pediatric Epilepsy Program
Massachusetts General Hospital

CBD-OS Efficacy in LGS and DS
Kevan VanLandingham, MD, PhD
Senior Medical Director
GW Pharmaceuticals

CBD-OS Safety
Stephen Wright, MD, PhD
Senior Medical Advisor
GW Pharmaceuticals

Clinical Perspective: CBD-OS Adjunctive Therapy in LGS and DS
Orrin Devinsky, MD
Director, Comprehensive Epilepsy Center
NYU Langone Health
FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
April 19, 2018

AGENDA (cont.)

9:00 a.m. Clarifying Questions

9:15 a.m. **FDA PRESENTATIONS**

Overview of Efficacy and Safety of Cannabidiol in Patients with Lennox-Gastaut Syndrome and Dravet Syndrome

Natalie Getzoff, MD
Clinical Reviewer
DNP, ODE-I, OND, CDER, FDA

Review of Liver Safety for Cannabidiol

Lara Dimick-Santos, MD
Clinical Reviewer
Division of Gastroenterology and Inborn Errors Products (DGIEP)
Office of Drug Evaluation III (ODE-III)
OND, CDER, FDA

Abuse Potential Assessment for Cannabidiol

Katherine Bonson, PhD
Pharmacologist
Controlled Substance Staff (CSS)
Office of the Center Director (OCD)
CDER, FDA

10:00 a.m. Clarifying Questions

10:15 a.m. **BREAK**

10:30 a.m. **OPEN PUBLIC HEARING**

11:30 a.m. Questions to the Committee/Committee Discussion

12:30 p.m. **ADJOURNMENT**