

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Peripheral and Central Nervous System Drugs Advisory Committee (PCNS) Meeting
FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
April 19, 2018

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

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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**