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

DRAFT 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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DRAFT 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	**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 (CBD)	**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**	

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