Food and Drug Administration
Center for Drug Evaluation and Research

Summary Minutes of the Peripheral and Central Nervous System
Drugs Advisory Committee Meeting
April 19, 2018

Location: FDA White Oak Campus, Building 31 Conference Center, The Great Room (Rm. 1503), 10903 New Hampshire Ave, Silver Spring, Maryland.

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

These summary minutes for the April 19, 2018 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee of the Food and Drug Administration were approved on April 30, 2018.

I certify that I attended the April 19, 2018 meeting of the Peripheral and Central Nervous System Drugs Advisory Committee of the Food and Drug Administration and that these minutes accurately reflect what transpired.

/s/	**/s/**
Moon Hee V. Choi, PharmD	G. Caleb Alexander, MD, MS
Acting Designated Federal Officer, PCNS	Chairperson, PCNS

Summary Minutes of the Peripheral and Central Nervous System Drugs Advisory Committee Meeting
April 19, 2018

The following is the final report of the Peripheral and Central Nervous System Drugs Advisory Committee meeting held on April 19, 2018. A verbatim transcript will be available in approximately six weeks, sent to the Division of Neurology Products and posted on the FDA website at:

https://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/PeripheralandCentralNervousSystemDrugsAdvisoryCommittee/ucm597976.htm.

All external requests for the meeting transcript should be submitted to the CDER Freedom of Information Office.

The Peripheral and Central Nervous System Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research, met on April 19, 2018, at the FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503), 10903 New Hampshire Avenue, Silver Spring, Maryland. Prior to the meeting, the members and temporary voting members were provided the briefing materials from the FDA and GW Pharmaceuticals. The meeting was called to order by G. Caleb Alexander, MD, MS (Chairperson). The conflict of interest statement was read into the record by Moon Hee V. Choi, PharmD (Acting Designated Federal Officer). There were approximately 280 people in attendance. There were 13 Open Public Hearing (OPH) presentations.

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

Attendance:

Peripheral and Central Nervous System Drugs Advisory Committee Members Present (Voting): G. Caleb Alexander, MD, MS (Chairperson); Mark W. Green, MD, FAAN; David S. Knopman, MD; Richard J. Kryscio, PhD; Chiadi U. Onyike, MD, MHS; Joel S. Perlmutter, MD

Peripheral and Central Nervous System Drugs Advisory Committee Member Present (Non-Voting): Mark Forrest Gordon, MD (Industry Representative)

Peripheral and Central Nervous System Drugs Advisory Committee Members Not Present (Voting): Merit Cudkowicz, MD; Nathan B. Fountain, MD

Temporary Members (Voting): Jane B. Acri, PhD; Danielle Boyce, MPH (Patient Representative); José E. Cavazos, MD, PhD; Harriet de Wit, PhD; Richard P. Hoffman, PharmD (Acting Consumer Representative); John Mendelson, MD; Eluen Ann Yeh, MA, MD, FRCPC, Dip ABPN

FDA Participants (Non-Voting): Ellis Unger, MD; Robert Temple, MD; Billy Dunn, MD; Eric Bastings, MD; Teresa Buracchio, MD; Dominic Chiapperino, PhD

Acting Designated Federal Officer (Non-Voting): Moon Hee V. Choi, PharmD

Open Public Hearing Speakers: Evelyn Nussenbaum; Sam Vogelstein; Michael D. Privitera, MD; Nicole Villas (Dravet Syndrome Foundation); Stephen Carlin; Martina Bebin, MD, MPA (University of Alabama at Birmingham and Children's of Alabama); Katherine Treadaway and Tim Chapman; Lisa Smith; Philip M. Gattone M.Ed. and Polly VandereWoude (Epilepsy Foundation); Abby Hemani; Anders, Jennifer and Sage Newcomer; John Gilmore; John Gilmore on behalf of Christina SanInocencio (Lennox-Gastaut Syndrome Foundation)

The agenda was as follows:

Call to Order and Introduction of Committee	**G. Caleb Alexander, MD, MS** Chairperson, PCNS
Conflict of Interest Statement	**Moon Hee V. Choi, PharmD** Acting Designated Federal Officer, PCNS
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
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
Clarifying Questions	

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

Clarifying Questions

BREAK

OPEN PUBLIC HEARING

Questions to the Committee/Committee Discussion

ADJOURNMENT

Question to the Committee:

1. **VOTE:** Is the benefit-risk profile of cannabidiol favorable for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older?

   Vote Result: Yes: 13 No: 0 Abstain: 0

   Committee Discussion*: The committee unanimously agreed that the benefit-risk profile of cannabidiol was favorable for the treatment of seizures associated with Lennox-Gastaut syndrome and Dravet syndrome in patients 2 years of age and older. The committee members agreed that efficacy was well demonstrated in the studies and that the safety concerns could be managed with labeling, education and monitoring. Please see the transcript for details of the committee discussion.*

The meeting was adjourned at approximately 11:44 a.m.