

GEORGIA BOARD OF PHARMACY
Emergency Conference Call
2 Peachtree St., NW, 6th Floor
Atlanta, GA 30303
November 2, 2018
3:30 p.m.

The following Board members were present:

Bill Prather, President
Vicki Arnold, Vice-President
Carrie Ashbee
Michael Brinson
Mike Faulk
Lisa Harris
Hal Henderson

Staff present:

Eric Lacefield, Deputy Executive Director
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney

Open Session

President Prather established that a quorum was present and called the meeting to order at 3:31 p.m.

Michael Brinson made a motion to adopt Emergency Rule 480-34-0.35-.12 Additional Compounds under Schedule V. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-0.35-.12 Additional Compounds under Schedule V

(1) This rule was adopted to protect the health, safety, and welfare of the public. This rule places an additional compound as specifically identified here under Schedule V of the Georgia Controlled Substances Act, Section 16-13-29 as follows:

(1.5) Epidiolex: A drug product in finished dosage formulation in its original container that has been approved by and labelled in compliance with the U.S. Food and Drug Administration (FDA) that contains cannabidiol (CBD) derived from cannabis and no more than 0.1 percent (w/w) residual tetrahydrocannabinols.

(2) This rule is based on the following findings of the Board:

(a) that the FDA approved the drug Epidiolex for the treatment of seizures associated with two rare and severe forms of epilepsy, Lennox-Gastaut syndrome and Dravet syndrome, in patients two years of age and older. Epidiolex is an oral solution that contains CBD extracted from the cannabis plant.

(b) that the U.S. Drug Enforcement Administration (DEA) did seek a medical and scientific evaluation or scheduling recommendation from the U.S. Department of Health and Human Services (HHS) with respect to the Epidiolex formulation. In responding to that request, HHS advised DEA that it found the Epidiolex formulation to have a very low potential for abuse and therefore, recommended that if DEA concluded that control of the drug was required under the Single Convention, Epidiolex should be placed in Schedule V of the Federal Controlled Substance Act (CSA).

(c) that the Board has considered, based on available information, the potential for abuse; scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; and the potential of the drug to produce psychic or physiological dependence liability.

The Board addressed this matter pursuant to O.C.G.A. § 50-14-1(3) as it determined that circumstances existed warranting the holding of this meeting on less than 24 hours' notice. These circumstances were the imminent threat to public health, safety, and welfare. As such, it found the immediate action of adopting Emergency Rule 480-34-0.35-.12 Additional Compounds under Schedule V, imperative.

There being no further business to discuss, the meeting was adjourned at 3:35 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, November 14, 2018 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

Minutes recorded by Kimberly Emm, Attorney
Minutes edited by Tanja D. Battle, Executive Director