



Mark R. Elam, Chairman
Charles M. Joye, II, P.E., Secretary
J.B. (Sonny) Kinney
Seema Shrivastava-Patel

Board:
Richard V. Lee, Jr.
Alex A. Singleton
Jim P. Creel, Jr.

Minutes of the July 11, 2019, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, July 11, 2019, at 10:00 a.m. in the Boardroom (#3420) at the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Mark Elam, Chairman
J.B. (Sonny) Kinney, 1st District
Charles M. Joye, II, P.E., 3rd District
Alex A. Singleton, 6th District

In attendance via telephone
Seema Shrivastava-Patel, 2nd District
Richard V. Lee, Jr., 5th District
Jim Creel, Jr., 7th District.

4th Congressional District seat is currently vacant.

Also, in attendance were Richard K. Toomey, Director; W. Marshall Taylor, Legal Counsel; Lisa Lucas Longshore, Clerk, M. Denise Crawford, Assistant Clerk; and Department staff.

Chairman Elam called the meeting to order and stated notice of this meeting had been provided to all persons, organizations and news media, which have requested notification, as required by Section 30-4-80(e) of the South Carolina Code of Laws.

Item 1: Minutes of May 9, 2019 meeting (Attachment 1-1)

Mr. Joye moved, seconded by Mr. Creel, to approve the minutes as presented. The Board voted and Motion carried.

Item 2: Placement of Brexanolone into Schedule IV of SC Controlled Substance Act (Attachment 2-1)

Ms. Heather Diebold, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

On June 10, 2019, The U.S. Department of Justice, Drug Enforcement Administration (DEA), issued an interim final rule placing brexanolone and its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible in schedule IV

of the federal Controlled Substance Act, effective June 17, 2019. F.R. Volume 84, Number 116, pp. 27938-27943.

Brexanolone is a new molecular entity with central nervous system depressant properties, and the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration have recently approved the use of brexanolone for intravenous use to treat postpartum depression ("PPD") in adult women.

According to its interim final rule, the DEA has concluded brexanolone has a low potential for abuse relative to the drugs or other substances in schedule III, a currently accepted medical use in the United States, and may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III; therefore, brexanolone should be placed in schedule IV of the federal Controlled Substances Act effective June 17, 2019.

After discussion, **Mr. Creel moved, seconded by Mr. Kinney, to designate additional substances named in the DEA Notice published in the Federal Register on June 17, 2019 and amend Section 44-53-250 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.** Scheduling document signed by Board Chairman. (Attachment 2-2)

Item 3: Placement of Solriamfetol into Schedule IV of SC Controlled Substance Act
(Attachment 3-1)

Ms. Heather Diebold, Bureau of Drug Control, presented this item to the Board.

Controlled substances are governed by the South Carolina Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the South Carolina Code of Laws. Schedule IV substances are listed in Section 44-53-250 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances shall be made," controlled substances are generally designated by the General Assembly upon recommendation by DHEC. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

Solriamfetol is a new molecular entity with central nervous system stimulant properties, and the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration have recently approved the use of solriamfetol to improve wakefulness in adult patients with excessive daytime sleepiness associated with narcolepsy or obstructive sleep apnea.

According to its interim final rule, the DEA has concluded solriamfetol has a low potential for abuse relative to the drugs or other substances in schedule III, a currently accepted medical use in the United States, and may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III; therefore, solriamfetol should be placed in schedule IV of the federal Controlled Substances Act effective June 17, 2019.

After discussion, Mr. Creel moved, seconded by Mr. Kinney, to designate additional substances named in the DEA Notice published in the Federal Register on June 17, 2019 and amend Section 44-53-250 of the S.C. Controlled Substances Act for

consistency with the Federal scheduling. The Board voted and Motion carried.
Scheduling document signed by Board Chairman. (Attachment 3-2)

Item 4: 2020 Proposed Meeting Dates for the SC Board of Health and Environmental Control (Attachment 4-1)

Mr. Kinney moved, seconded by Mr. Singleton, to approve the proposed 2020 meeting dates as presented. The Board voted and Motion carried.

Item 5: Executive Session

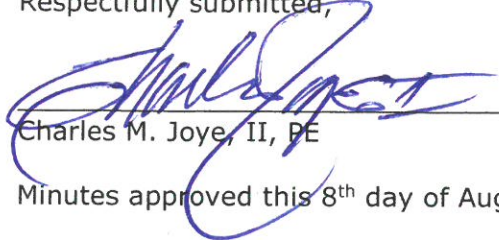
Mr. Joye made a motion that the Board go into Executive Session pursuant to SC Code Section 30-4-70(A)(1) and (A)(2) to discuss an employment matter. Mr. Singleton seconded the motion and the motion carried unanimously.

Chairman Elam stated the Board was back in public session and while in Executive Session no actions were taken.

Being no further business, Chairman Elam adjourned the meeting.

All referenced attachments are made a permanent part of these minutes.

Respectfully submitted,



Charles M. Joye, II, PE

Minutes approved this 8th day of August 2019.

ATTEST:



Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 1-1 May 9, 2019 minutes
- 2-1 Placement of Brexanolone into Schedule IV of SC Controlled Substance Act
- 2-2 Board Scheduling Document
- 3-1 Placement of Solriamfetol into Schedule IV of SC Controlled Substance Act
- 3-2 Board Scheduling Document
- 4-1 2020 Proposed Meeting Dates for the SC Board of Health and Environmental Control