



Board:

Mark R. Elam, Chairman
Jim P. Creel, Jr., Vice-Chairman
Charles M. Joye, II, P.E., Secretary
J.B. (Sonny) Kinney

Seema Shrivastava-Patel
Richard V. Lee, Jr.
Alex A. Singleton

**Minutes of the April 9, 2020, meeting of the
South Carolina Board of Health and Environmental Control**

The South Carolina Board of Health and Environmental Control met on Thursday, April 9, 2020, 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:

Richard V. Lee, Jr., 5th District

In attendance via telephone:

Mark Elam, Chairman
Jim P. Creel, Jr., Vice-Chairman
J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, 2nd District
Charles M. Joye, II, P.E., 3rd District
Alex A. Singleton, 6th District

The 4th Congressional District seat is currently vacant.

Also, in attendance were Richard K. Toomey, Director, Ashley Biggers, Legal Counsel; M. Denise Crawford, Clerk; Department staff, and a member of the public.

Chairman Elam and Vice Chairman Creel attended by telephone, and Mr. Lee assumed the Chair to conduct the meeting. Mr. Lee 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 March 12, 2020 meeting (Attachment 1-1)

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

Item 2: Request for Placement of Cenobamate into Schedule V for Controlled Substances in South Carolina (Attachment 2-1)

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, Health Quality presented this matter to the Board.

Controlled substances are governed by the Controlled Substances Act ("CSA"), Title 44, Chapter 53 of the S.C. Code of Laws. Schedule V substances are listed in Section 44-53-270. Section 44-53-160 is titled, "Manner in which changes in schedule of controlled substances shall be made." Pursuant to Section 44-53-160, controlled substances are

generally designated by the General Assembly upon recommendation by the Department of Health and Environmental Control ("Department"). Section 44-53-160(C) provides a process by which the Department can expeditiously designate a substance as a controlled substance if the federal government has designated the substance as such.

South Carolina Code Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On November 21, 2019, the U.S. Food and Drug Administration ("FDA") approved a new drug application for XCOPRI (cenobamate) tablets. Cenobamate is chemically known as [(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate. The U.S. Department of Health and Human Services ("DHHS") provided the federal Drug Enforcement Administration ("DEA") with a recommendation that cenobamate be placed in schedule V of the Federal Controlled Substances Act ("Federal CSA"). In accordance with the Federal CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing cenobamate and its salts in schedule V of the Federal CSA, effective March 10, 2020, in the *Federal Register*, Volume 85, Number 47, pages 13741-13746; [https:// govinfo.gov/content/pkg/FR-2020-03-10/pdf/2020-04963.pdf](https://govinfo.gov/content/pkg/FR-2020-03-10/pdf/2020-04963.pdf).

Cenobamate is a new molecular entity with central nervous system ("CNS") depressant properties. Cenobamate is a voltagegated sodium channel ("NaV") blocker that also has gamma-aminobutyric acid (GABA)-A channel positive allosteric modulator ("PAM") activity. On November 21, 2018, SK Life Science ("Sponsor") submitted a new drug application ("NDA") to the FDA for cenobamate 12.5, 25, 50, 100, 150, and 200 mg oral tablets. On November 22, 2019, the DEA received notification that the FDA approved the NDA on November 21, 2019 for the treatment of partial-onset seizures in adult patients.

The DEA received a letter on December 10, 2019 from the DHHS, dated December 3, 2019, that contained a scientific and medical evaluation document prepared by the FDA related to cenobamate. This document contained an eight-factor analysis of the abuse potential of cenobamate, along with the DHHS' recommendation to control cenobamate under schedule V of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the DHHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA

concluded that cenobamate met the 21 U.S.C. 812(b)(5) criteria for placement in schedule V of the CSA.

21 U.S.C. 812(b) requires the evaluation of a substance's abuse potential, accepted medical use, and safety for use under medical supervision for scheduling under the CSA as a controlled substance. After consideration of the above eight-factor determination of control of a substance found in 21 U.S.C. 811(c), and a review of the scientific and medical evaluation, and scheduling recommendation provided by DHHS, the DEA finds that cenobamate meets the following criteria for placement in schedule V of the CSA pursuant to 21 U.S.C. 812(b)(5):

1. Cenobamate has a low potential for abuse relative to the drugs or other substances in Schedule IV. Cenobamate, similar to the schedule IV substance lacosamide, which is a voltagegated sodium channel blocker that also has GABA-A channel PAM activity, similar to schedule IV benzodiazepines. In drug discrimination studies, cenobamate partially generalized to the discriminative stimulus effects of midazolam (schedule IV) but fully generalized to the discriminative stimulus effects of chlordiazepoxide (schedule IV) in rats. In self-administration studies, cenobamate was self-administered by rodents, but the self-administration (i.e., number of infusions) of cenobamate was lower than that of midazolam. In the HAP studies, cenobamate produced drug-liking scores higher than placebo but less than that of alprazolam, a schedule IV substance. Based on all of these studies, the DHHS concluded that cenobamate has an abuse potential similar to that of substances in schedule V of the CSA. Thus, the DEA finds that the potential for abuse of cenobamate is less than that of schedule IV benzodiazepines but similar to that of substances in schedule V of the CSA.
2. Cenobamate has a currently accepted medical use in the United States. The FDA recently approved the NDA for cenobamate for partial-onset seizures in adult patients. Therefore, cenobamate has a currently accepted medical use in treatment in the United States.
3. Abuse of cenobamate may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. Cenobamate may lead to physical or psychological dependence that is low relative to substances in schedule IV, and similar to that of substances in schedule V.

The Acting Administrator of the DEA concluded that cenobamate, including its salts, warrants control in schedule V of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended the placement of cenobamate in Schedule V for controlled substances in South Carolina and the amendment of Section 44-53-270 of the South Carolina Code of Laws to include:

() Cenobamate ([(1R)-1-(2-chlorophenyl)-2-(tetrazol-2-yl)ethyl] carbamate; 2H-tetrazole-2-ethanol, alpha-(2-chlorophenyl)-, carbamate (ester), (alphaR)-; carbamic acid (R)-(+) -1-(2-chlorophenyl)-2-(2H-tetrazol-2-yl)ethyl ester).

The Department recommended the Board place cenobamate in Schedule V of the South Carolina Controlled Substances Act.

After discussion, **Mr. Creel moved, seconded by Mr. Singleton, to designate the additional substances named in the DEA Notice published in the Federal Register on March 10, 2020 and amend Section 44-53-270 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.** Designation Order signed by Chairman Elam (Attachment 2-2)

Item 3: Request for Placement of Lemborexant into Schedule IV for Controlled Substances in South Carolina. (Attachment 3-1)

Ms. Christie Frick, Director, Prescription Monitoring Program, Bureau of Drug Control, Health Quality presented this matter to the Board.

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

South Carolina Code Section 44-53-160(C) states:

If a substance is added, deleted, or rescheduled as a controlled substance pursuant to federal law or regulation, the department shall, at the first regular or special meeting of the South Carolina Board of Health and Environmental Control within thirty days after publication in the federal register of the final order designating the substance as a controlled substance or rescheduling or deleting the substance, add, delete, or reschedule the substance in the appropriate schedule. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection has the full force of law unless overturned by the General Assembly. The addition, deletion, or rescheduling of a substance by the department pursuant to this subsection must be in substance identical with the order published in the federal register effecting the change in federal status of the substance. Upon the addition, deletion, or rescheduling of a substance, the department shall forward copies of the change to the Chairman of the Medical Affairs Committee and the Judiciary Committee of the Senate, the Medical, Military, Public and Municipal Affairs Committee and the Judiciary Committee of the House of Representatives, and to the Clerks of the Senate and House, and shall post the schedules on the department's website indicating the change and specifying the effective date of the change.

On December 20, 2019, the U.S. Food and Drug Administration ("FDA") approved a new drug application for Dayvigo (lemborexant) tablets for oral use. Lemborexant is chemically known as (1R,2S)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-N-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide. The federal Department of Health and Human Services ("DHHS") provided the federal Drug Enforcement Administration ("DEA") with a recommendation that lemborexant be placed in schedule IV of the federal Controlled Substances Act ("federal CSA"). In accordance with the federal CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA issued an interim final rule placing lemborexant, including 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 CSA, effective April 7, 2020, in *Federal Register*, Volume 85, Number 67, pages 19387-19391; <https://www.govinfo.gov/content/pkg/FR-2020-04-07/pdf/2020-07089.pdf>.

Lemborexant [(1R,2S)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-N-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide] is a new molecular entity with central nervous system ("CNS") depressant properties. Lemborexant acts as an antagonist at both orexin-1 and orexin-2 receptors. On December 27, 2018, Eisai, Inc., ("Sponsor") submitted a new drug application ("NDA") to FDA for Dayvigo (lemborexant), 5 and 10 mg oral tablets, with the proposed dosage suggestion of 5 mg, not to exceed a maximum dose of 10 mg once a day. On March 9, 2020, DEA received notification that FDA approved, on December 20, 2019, NDA for Dayvigo (lemborexant) for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance.

On January 9, 2020, the DEA received from the DHHS a scientific and medical evaluation document dated December 19, 2019 prepared by the FDA related to lemborexant. This document contained an eight-factor analysis of the abuse potential of lemborexant, along with DHHS' recommendation to control lemborexant under schedule IV of the South Carolina CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the DHHS, along with all other relevant data, and completed its own eight-factor review document pursuant to 21 U.S.C. 811(c). The DEA concluded that lemborexant met the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the South Carolina CSA.

21 U.S.C. 812(b) requires the evaluation of a substance's abuse potential, accepted medical use, and safety for use under medical supervision for scheduling under the South Carolina CSA as a controlled substance. After consideration of the above eight factors determinative of control of a substance (21 U.S.C. 811(c)), and a review of the scientific and medical evaluation and scheduling recommendation provided by DHHS, DEA finds that lemborexant meets the following criteria for placement in schedule IV of the CSA pursuant to 21 U.S.C. 812(b)(4):

- 1) Lemborexant has a low potential for abuse relative to the drugs or other substances in schedule III. Lemborexant is a dual orexin receptor antagonist, which produces sedation in human behavioral studies. In the HAP study, therapeutic and suprathreshold doses of lemborexant produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, Stoned, and Take Drug Again that were statistically significantly greater than those produced by placebo. These responses of lemborexant are similar to those produced by schedule IV drugs suvorexant and zolpidem. Because lemborexant is similar to zolpidem and suvorexant in its abuse potential, lemborexant has a low potential for abuse relative to the drugs and other listed substances in schedule III of the CSA.
- 2) Lemborexant has a currently accepted medical use in the United States. FDA recently approved lemborexant oral tablets for the treatment of adult patients with insomnia, characterized by difficulties with sleep onset and/or sleep maintenance. Thus, lemborexant has a currently accepted medical use in treatment in the United States.
- 3) Lemborexant may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III. In the HAP study,

lemborexant produced positive subjective responses to measures such as Drug Liking, Overall Drug Liking, Good Drug Effects, High, Stoned, and Take Drug Again that were greater than placebo and similar to that of the schedule IV drugs zolpidem and suvorexant. This data suggests that lemborexant can produce psychic dependence to a similar extent as zolpidem and suvorexant. Thus, abuse of lemborexant may lead to limited psychological dependence relative to the drugs or other substances in schedule III.

The Acting Administrator of the DEA concludes that lemborexant, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, warrants control in schedule IV of the South Carolina CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended the placement of lemborexant in Schedule IV for controlled substances in South Carolina and the amendment of Section 44-53-250 of the South Carolina Code of Laws to include:

() Lemborexant (1R,2S)-2-[(2,4-dimethylpyrimidin-5-yl)oxymethyl]-2-(3-fluorophenyl)-N-(5-fluoropyridin-2-yl)cyclopropane-1-carboxamide.

The Department recommended the Board place lemborexant in Schedule IV of the South Carolina Controlled Substances Act.

After discussion, **Mr. Creel moved, seconded by Mr. Singleton, to designate the additional substances named in the DEA Notice published in the Federal Register on April 7, 2020 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.** Designation Order signed by Chairman Elam (Attachment 2-2)

Item 4: Agency Affairs

Dr. Brannon Traxler, Physician Consultant, Division of Acute Disease Epidemiology, Bureau of Public Health Preparedness, provided an update on the COVID 19 (Coronavirus).

After discussion, **the Board accepted this as information.**

Rob Wronski, Chief, Bureau of Emergency Medical Services, provided information on the EMS response to COVID-19 and the HCR 911 Network.

After discussion, **the Board accepted this as information.**

Item 5: Final Review Conference - Docket No. 20-RFR-10, Coastal Timber Co. Dam (D3622) - Hazard Classification Change for Coastal Timber Co. Dam (D3622), Horry County

A Final Review Conference was held concerning a staff decision, if upheld, would change the hazard classification for Coastal Timber Co. Dam (D3622). Mr. Lee announced the agenda item and asked Ms. Biggers to introduce the matter.

Ms. Jill Stewart, Mr. John McCain, and Mr. Nathan Haber, Esquire represented the Department. Ms. Stewart and Mr. McCain presented a PowerPoint presentation to the Board.

Mr. Wendell Norris, owner of Coastal Timber Company Dam represented Coastal Timber Co. Dam. Mr. Norris presented 21 photographs to the Board.

Ann Clark, John McCain, and Wendell Norris were sworn in as witnesses in this matter.

After discussion, **Mr. Lee moved, seconded by Mr. Creel, to go into Executive Session for the purpose of deliberations and legal advice in this matter. The Board voted and Motion carried.**


Mr. Lee announced the Board was back in public session and while in Executive Session, no actions were taken.

After further discussion, **Mr. Singleton moved, seconded by Mr. Lee to uphold the staff decision. The Board voted and the Motion carried.**

Being no further business, the Chairman adjourned the meeting.

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

Respectfully submitted,



Charles M. Joyce, II, PE

Minutes approved this 7th day of May 2020.

ATTEST:



Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 March 12, 2020 minutes
- 2-1 Request for Placement of Cenobamate into Schedule V for Controlled Substances in South Carolina

- 3-1 Request for Placement of Lemborexant into Schedule IV for Controlled Substances in South Carolina
- 5-1 Final Review Conference - Docket No. 20-RFR-10, Coastal Timber Co. Dam (D3622) - Hazard Classification Change for Coastal Timber Co. Dam (D3622), Horry County
- 5-2 Staff PowerPoint
- 5-3 Photographs provided by Mr. Norris