Minutes of the February 13, 2020, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, February 13, 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:

J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, 2nd District
Richard V. Lee, Jr., 5th District
Alex A. Singleton, 6th District

In attendance via telephone
Mark Elam, Chairman
Charles M. Joye, II, P.E., 3rd District

Not in attendance
Jim P. Creel, Jr., Vice-Chairman

The 4th Congressional District seat is currently vacant.

Also, in attendance were Richard K. Toomey, Director, W. Marshall Taylor, Jr., Legal Counsel; M. Denise Crawford, Clerk; Department staff, and members of the public.

Chairman Elam attended by telephone and Vice Chairman Creel was absent, 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 January 6, 2020 meeting (Attachment 1-1)

Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to approve the minutes as presented. The Board voted and Motion carried.

Item 2: Administrative and Consent Orders issued by Health Regulation (Attachment 2-1)

Ms. Bentley White, Director, Health Regulation Policy and Communications, stated for this reporting period, three (3) Consent Orders had been issued with assessed penalties totaling $33,600.00.

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

Item 3: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 3-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, eighty-one (81) Consent Orders with assessed civil penalties totaling $117,940.00 and five (5) Administrative Orders with assessed civil penalties totaling $67,604.00 had been issued.

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

Item 4: Notice of Proposed Regulation amending Regulation 61-63, *Radioactive Materials (Title A)*, Exempt from General Assembly review

Ms. Stacey French, Director, Division of Waste Management, Environmental Affairs, Bureau of Land and Waste Management, presented this item to the Board.

The Bureau of Land and Waste Management proposed the Notice of Proposed Regulation amending R.61-63, *Radioactive Materials (Title A)*, for publication in the February 28, 2020, *South Carolina State Register*. Legal authority resides in S.C. Code Section 13-7-70 (Supp 2016), which designates the Department of Health and Environmental Control as the agency responsible for the control and regulation of radiation sources. The Administrative Procedures Act, S.C. Code Section 1-23-120(H)(1), exempts these amendments from General Assembly review, as the Department proposed these amendments for compliance with federal law.

Pursuant to the Federal Atomic Energy Act of 1954, the United States Nuclear Regulatory Commission ("Commission") enters into agreements with state governors allowing for state regulation of byproduct, source, and special nuclear materials. 42 U.S.C. Section 2121. The Commission enters into such agreements if it finds the state regulatory program is complying with applicable federal regulations. *Id*. To renew South Carolina's ongoing agreement with the Commission, the Bureau requested approval to amend R.61-63, ensuring state standards comply with the Commission's regulatory updates. The proposed amendments add clarifications or corrections to Part II of the regulation. Additionally, the proposed amendments authorize the Department to review their general licensees' quality assurance program for the use of Commission-approved Type B packaging for transportation of radioactive material as required in NRC Regulation Title 10, Code of Federal Regulation Part 71.

The Department had a Notice of Drafting published October 25, 2019, *State Register*. The Department received no public comments November 25, 2019, the close of public comment period.

The Bureau held a stakeholder meeting on November 14, 2019, with *EnergySolutions* to discuss the schedule and implementation process for the proposed amendments.

The Bureau submitted draft text of the proposed amendments to the Technical Advisory Radiation Control Council ("TARCC") on January 7, 2020, for review. The Bureau received no comments from TARCC resulting from the review.

Department staff conducted an internal review of the proposed amendments on January 14, 2020.

The Bureau submitted copies of the proposed regulations to the Commission for a compatibility review on June 7, 2017. The Commission responded with comments dated July 25, 2017. The Bureau integrated these comments into the proposed amendments where applicable.

After discussion, **Mr. Singleton moved, seconded by Mr. Kinney, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-63, *Radioactive Materials*, in the *State Register*, to provide opportunity for public comment, to receive and consider comments, and allow staff to proceed with a public hearing before the Board. The Board voted and Motion carried.**

Item 5: Placement of Lasmiditan into Schedule V for SC Controlled Substances Act
(Attachment 5-1)

Ms. Christie Frick, Director, Prescription Monitoring Program, Health Regulations, Bureau of Drug Control, presented this item 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 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.

On October 11, 2019, the U.S. Food and Drug Administration ("FDA") approved a new drug application for Reyvow (lasmiditan). Lasmiditan is chemically known as 2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide. The federal Department of Health and Human Services ("HHS") provided the federal Drug Enforcement Administration ("DEA") with a recommendation that lasmiditan 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 lasmiditan (including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible) in schedule V of the federal CSA, effective January 31, 2020, in *Federal Register*, Volume 85, Number 21, pages 5557-5562; https://www.govinfo.gov/content/pkg/FR-2020-01-31/pdf/2020-01957.pdf.

Lasmiditan (2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide) is a new molecular entity with central nervous system ("CNS") depressant properties. Lasmiditan is a 5-hydroxytryptamine (5-HT, serotonin) 1F receptor agonist. One of its metabolites has low GABA channel positive allosteric activity. On October 11, 2018, Eli Lilly and Company ("Sponsor") submitted a new drug application ("NDA") for lasmiditan to the FDA for Reyvow (lasmiditan) 50 and 100 mg oral tablets. On November 4, 2019, the DEA received notification that FDA approved, on October 11, 2019, the NDA for Reyvow (lasmiditan) for the acute treatment of migraine with or without aura in adults.

On November 4, 2019, the DEA received from the HHS a scientific and medical evaluation document dated October 23, 2019 prepared by the FDA related to lasmiditan. This document contained an eight-factor analysis of the abuse potential of lasmiditan, along with HHS' recommendation to control lasmiditan under schedule V of the CSA. In response, the DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by the HHS, 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 lasmiditan 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 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 HHS, DEA finds that lasmiditan meets the following criteria for placement in schedule V of the CSA pursuant to 21 U.S.C. 812(b)(5):

1) Lasmiditan has a low potential for abuse relative to the drugs or other substances in Schedule IV. Lasmiditan, a 5– HT1F receptor agonist, did not bind to receptors typically associated with abuse (*e.g.,* opioid, cannabinoid, GABAergic). In the drug discrimination paradigm, lasmiditan did not generalize to the discriminative stimulus effects of the benzodiazepine lorazepam. Lasmiditan did, however, produce reinforcing effects in the self-administration assay. As detailed by HHS, in a human abuse-potential study, all doses of lasmiditan produced drug-liking scores that were significantly higher than that of placebo, indicating its abuse potential. Subjects following lasmiditan reported drug-liking scores that were significantly smaller than that of alprazolam (schedule IV drug), indicating that its abuse potential is less than that of alprazolam. Lasmiditan produced abuse-related adverse events to a greater extent than that of placebo, but with low frequency.

2) Lasmiditan has a currently accepted medical use in the United States. The FDA recently approved the NDA for lasmiditan oral tablets for the acute treatment of migraine with or without aura in adults. Therefore, lasmiditan has a currently accepted medical use in treatment in the United States.

3) Abuse of lasmiditan may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV. Lasmiditan 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 concludes that lasmiditan, 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 V of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommended the placement of lasmiditan 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: Lasmiditan (2,4,6-trifluoro-*N*-(6-(1-methylpiperidine-4-carbonyl)pyridine-2-yl-benzamide) including its salts, isomers, and salts of isomers.

After discussion, **Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to designate the additional substances named in the DEA Notice published in the Federal Register on January 31, 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 5-2)

Item 6: Agency Affairs

Dr. Michael Kacka, Medical Consultant, Division of Acute Disease Epidemiology, Public Health, provided an update on the COVID 19 (Coronavirus).

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

Myra Reece, Director of Environmental Affairs, along with the staff from the Bureau of Land and Waste Management, made a presentation about the *Don't Waste Food South Carolina* campaign. Director Toomey and Ms. Reece were recognized as Ambassadors of the campaign.

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

Richard K. Toomey, Director, updated the Board on:
- the new DHEC campaign "Stronger Together";
- Public Health Accreditation;
- the Bureau of Economic Advisors meeting;
- the budget presentation to the Legislature;
- the new Director of Public Health.

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

Item 7: Executive Session

Mr. Singleton made a motion that the Board go into Executive Session pursuant to SC Code Section 30-4-70(A)(1) and (A)(2) to obtain legal advice related to a Heath Regulation matter. Ms. Shrivastava-Patel seconded the motion and the motion carried unanimously.

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

Being no further business, Mr. Lee adjourned the meeting.

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

Respectfully submitted,

Charles M. Joye, II, PE

Minutes approved this 12th day of March 2020.

ATTEST:

Richard V. Lee, Jr., 5th District

Attachments

0-1 Agenda
0-2 Sign in Sheet
1-1 January 6, 2020 minutes
2-1 Administrative and Consent Orders issued by Health Regulation
3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
4-1 Notice of Proposed Regulation amending Regulation 61-63, *Radioactive Materials (Title A),* Exempt from General Assembly review
5-1 Placement of Lasmiditan into Schedule V for SC Controlled Substances Act