Minutes of the May 5, 2022, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, May 5, 2022, at 11:00 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:

Robert Bolchoz, Chairman
J.B. (Sonny) Kinney, 1st District
Seema Shrivastava-Patel, Vice-Chairwoman, 2nd District
Richard V. Lee, Jr., 5th District
Morris E. Brown, III, MD, 6th District

In attendance virtually:
Charles M. Joye, II, P.E., 3rd District

Not in attendance:
Robert Morgan, MD, 4th District
Jim P. Creel, Jr., 7th District

Also, in attendance were Dr. Edward Simmer, Director; W. Marshall Taylor, General Counsel; M. Denise Crawford, Clerk; Department staff; and members of the public. The meeting was also available via Livestream. (Attachment 0-2)

Chairman Bolchoz 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.

Chairman Bolchoz stated that a change had been made to the agenda. Current agenda item number 8 would move up to agenda item 7, and current agenda item number 7 would move to number 8.

Item 1: Minutes of April 7, 2022 meeting (Attachment 1-1)

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

Item 2: Agency Affairs

Dr. Edward Simmer, Director, updated the Board on

- Public Service Recognition Week
- Earth Day
- Myra Reece, Director of Environmental Affairs, was recognized for over thirty-five years of service and for her recent appointment as President of the Environmental Council of States. She was presented with a DHEC Appreciation Coin
- 2022-2023 Budget request
- CON Bill
- Compassionate Care / Medical Marijuana Bill
- Senate Bill S.2
- COVID 19
- Keith Frost, former COVID 19 Incident Commander, was recognized for his service during the COVID 19 response. He was presented with a Certificate
- Community gardens
- SHaPE SC
- Paul Lee, Manager for Environmental Emergency Response, provided an overview of the program

Mr. Lee informed the Board that following receipt the data concerning drug overdoses that was provided by staff, he reached out to a local radio station and coordinated an appearance with Tramaine McMullen, Opioid Grants Manager. He recognized Dr. McMullen for her work.

Item 3: Administrative Orders and Consent Orders issued by Healthcare Quality (Attachment 3-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, five (5) Consent Orders with assessed civil penalties totaling $61,400.00 and no Administrative Orders were issued.

Mr. Lee asked about Pacifica Senior Living and what the prior actions indicate. Ms. White replied that it indicated previous enforcement actions. Mr. Kinney followed up for additional clarification, and Ms. White stated that the facility would have to provide a plan of corrective action to show preventative and corrective action.

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

Item 4: Administrative Orders and Consent Orders issued by Environmental Affairs (Attachment 4-1)

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, forty-four (44) Consent Orders with assessed civil penalties totaling $271,920.00 and ten (10) Administrative Orders with assessed civil penalties totaling $93,200.00 were issued.

Mr. Lee asked about the Roper Hospital and St. Francis Hospital fines and if training was being put in place for these types of violations. Ms. Sproles asked Van Keisler, Director for the Compliance and Enforcement Division of the Bureau of Land and Waste Management to assist with answering the question. Mr. Keisler stated that the agency was in the process of putting together training for the hospitals. Mr. Lee went on to ask about certifications for hospitals on the handling of hazardous waste. Mr. Keisler stated that there was no certification, but that the hospitals were made aware of the requirements. Mr. Kinney followed up and asked about logs. Mr. Keisler indicated that logs were required.

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

Item 5: Request for Placement of Daridorexant in Schedule IV for Controlled Substances in South Carolina (Attachment 5-1)

Ms. Heather Diebold, Midlands District Director, Bureau of Drug Control, Healthcare Quality, 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 made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

On January 7, 2022, the United States Food and Drug Administration ("FDA") approved a new drug application for QUIVIVIQ (daridorexant) tablets for the treatment of adult patients with insomnia characterized by difficulties with sleep onset and/or sleep maintenance. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place daridorexant and its salts in schedule IV of the Controlled Substances Act ("CSA"). In accordance with the CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, DEA issued an interim final rule placing daridorexant in schedule IV, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation, thereby facilitating the commercial

distribution of QUIVIVIQ as a lawful controlled substance. This interim final became effective April 7, 2022, *Federal Register*, Volume 87, Number 67, pages 20313-20318; *https://* www.govinfo.gov/content/pkg/FR-2022-04-07/pdf/2022-07322.pdf.

On December 22, 2021, DEA received from HHS a scientific and medical evaluation entitled "Basis for the Recommendation to Control Daridorexant and its Salts in schedule IV of the Controlled Substances Act" and a scheduling recommendation. Pursuant to 21 U.S.C. 811(b) and (c), this document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of daridorexant, along with HHS's recommendation to control daridorexant and its salts under schedule IV of the CSA. In response, DEA reviewed the scientific and medical evaluation and scheduling recommendation provided by HHS, along with all other relevant data, and completed its own eight-factor review pursuant to 21 U.S.C. 811(c). DEA concluded that daridorexant meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of the CSA. Pursuant to subsection 811(j), and based on HHS' scheduling recommendation, the approval of the NDA by HHS/FDA, and DEA's determination, DEA is issuing this IFR to schedule daridorexant as a schedule IV controlled substance under the CSA.

The CSA lists the findings required to place a drug or other substance in any particular schedule (I, II, III, IV, or V). 21 U.S.C. 812(b). After consideration of the analysis and recommendation of the Assistant Secretary for Health of HHS and review of all available data, the Administrator of DEA ("Administrator"), pursuant to 21 U.S.C. 812(b)(4), finds that:

1) Daridorexant has a low potential for abuse relative to the drugs or other substances in Schedule III.

2) Daridorexant has a currently accepted medical use in treatment in the United States.

3) Abuse of daridorexant may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule III.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommended placing daridorexant in schedule IV including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of such isomers is possible within the specific chemical designation and the amendment of Section 44-53-250 of the South Carolina Controlled Substances Act.

After discussion, **Mr. Kinney moved, seconded by Mr. Lee, to designate Daridorexant and the additional substances named in the DEA Notice published in the Federal Register on April 7, 2022, and amend Section 44-**

53-250 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.

Item 6: Request for Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I for Controlled Substances in South Carolina (Attachment 6-1)

Ms. Heather Diebold, Midlands District Director, Bureau of Drug Control, Healthcare Quality, 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 I substances are listed in Section 44-53-190 of the South Carolina Code of Laws. Pursuant to Section 44-53-160, titled "Manner in which changes in schedule of controlled substances made," controlled substances are generally designated by the General Assembly upon recommendation by the Department. Section 44-53-160(C) provides a process for the Department to expeditiously designate a substance if the federal government has so designated.

On April 12, 2022, the Administrator of the Drug Enforcement Administration ("DEA") issued a temporary order to schedule seven synthetic benzimidazole-opioid substances, Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene, in schedule I of the Controlled Substances Act ("CSA"). This action is based on a finding by the Administrator that the placement of these seven substances in schedule I is necessary to avoid imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis with, or possess) or propose to handle these seven specified controlled substances. This final rule was published with an effective date of April 12, 2022, *Federal Register*, Volume 87, Number 70, pages 21556-21561; *https://www.govinfo.gov/content/pkg/FR-2022-04-12/pdf/2022-07640.pdf.*

To find that temporarily placing a substance in schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator must consider three of the eight factors set forth in 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any risk there is to the public health. 21 U.S.C. 811(h)(3). This consideration includes any information indicating actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution of these substances. 21 U.S.C. 811(h)(3). Substances meeting the statutory requirements for temporary scheduling may only be placed in schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I have

high potential for abuse, no currently accepted medical use in treatment in the United States, and no accepted safety for use under medical supervision.

The United States currently is experiencing an opioid overdose epidemic, and the presence of synthetic opioids on the illicit drug market threatens to exacerbate this. The trafficking, continued evolution, and abuse of new synthetic opioids are deadly trends posing imminent hazards to public safety. Adverse health effects associated with abuse of synthetic opioids and increased popularity of these substances have been serious concerns in recent years. Butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene are synthetic opioids recently identified on the illicit drug market in the United States.

Data obtained from preclinical pharmacology studies show that butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene have pharmacological profiles similar to those of the potent benzimidazole-opioids etonitazene and isotonitazene, both schedule I controlled substances. Because of their pharmacological similarities, use of these seven benzimidazole-opioid substances presents a high risk of abuse and may negatively affect users and communities.

Available data and information for butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene indicate that these substances have high potential for abuse, no currently accepted medical use in treatment in the United States, and lack of accepted safety for use under medical supervision.

In accordance with 21 U.S.C. 811(h)(1) and (3), the Administrator considered available data and information, set forth the grounds for her determination that it is necessary to temporarily place butonitazene, etodesnitazene, flunitazene, metodesnitazene, metonitazene, N-pyrrolidino etonitazene, and protonitazene in schedule I of the CSA and finds that such placement is necessary to avoid an imminent hazard to the public safety.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommended placing Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers whenever the existence of such isomers, esters, ethers, and salts is possible, to Schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(B) of the South Carolina Controlled Substances Act.

After discussion, **Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to designate Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene and the additional substances named in the DEA Notice published in the Federal**

Register on April 12, 2022, and amend Section 44-53-190 (B) of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and the motion carried.

Chairman Bolchoz stated that the Board would take a five-minute break.

Item 7: Final Review Conference - Docket No. 22-RFR-12, The Red Brick Pizza. Issuance of Permit Suspension and Cease and Desist Order, Permit No. 15-206-00758, Colleton County (Attachment 7-1)

A Final Review Conference was held concerning a staff decision to issue a permit Suspension and Cease and Desist Order for permit number 15-206-00758, Colleton County. Chairman Bolchoz announced the agenda item and asked Mr. Taylor to introduce the matter.

David Stanfield, David Vaughan, and Timothy Kinney were sworn in as witnesses in this matter.

Mr. David Vaughan presented on behalf of the Department. The Department presented a PowerPoint on the matter. (Attachment 7-2)

Mr. David Stanfield presented for The Red Brick Pizza.

After presentations by the parties, questions by the Board, and discussion, **Ms. Shrivastava-Patel moved, seconded by Mr. Lee, to go into Executive Session for the purpose of deliberations and legal advice in this matter. The Board voted and Motion carried.**

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

After further discussion, **Ms. Shrivastava-Patel moved, seconded by Mr. Kinney to modify staff decision to allow the facility to operate on Wednesdays and Thursdays from 4:30 -900 PM and on Fridays and Saturdays from 4:30-930 PM subject to the following conditions:**

- **All permitting must be complete within eight (8) weeks from today**
- **Reduce to a forty (40) seat capacity**
- **If you operate outside of these hours or if permitting is not complete in eight (8) weeks or if system shows sign of overflow, permit is immediately suspended.**

Ms. Shrivastava-Patel further clarified that operation means "serving customers" and it was clarified if permitting was completed sooner than eight (8) weeks, the conditions would not apply and the facility could

operate as the new permit allowed. The Board voted and the Motion carried.

Item 8: Final Review Conference - Docket No. 22-RFR-11, Tom Rowland, Point Farm MB, Inc. Issuance of a critical area permit and coastal zone consistency certification for impacting tidelands critical areas on and adjacent to the North Edisto River and Leadenwah Creek at Point Farm Road, Wadmalaw Island, Charleston County. Permit No. OCRM03332 (Attachment 8-1)

A Final Review Conference was held concerning a staff decision to issue a critical area permit and coastal zone consistency certification for impacting tidelands critical areas on and adjacent to the North Edisto River and Leadenwah Creek at Point Farm Road, Wadmalaw Island, Charleston County. Chairman Bolchoz announced the agenda item and asked Mr. Taylor to introduce the matter.

Blair Williams, Sarah Reed, Ross Nelson, and Joe Kelley were sworn in as witnesses in this matter.

Mr. Blair Williams presented on behalf of the Department. The Department presented a PowerPoint on the matter. (Attachment 8-2)

Ms. Leslie Lenhardt, Esquire presented on behalf of the Requestors, Wadmalaw Island Land Planning Committee, South Carolina Coastal Conservation League, and John and Marilynn Hill. The Requestors presented a PowerPoint on the matter. (Attachment 8-3)

Ms. Mary Shahid, Esquire presented on behalf of the Applicant, Tom Rowland, Point Farm MB, Inc. The Applicant presented a PowerPoint on the matter. (Attachment 8-4)

After presentations by the parties, questions by the Board, and discussion, **Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to go into Executive Session for the purpose of deliberations and legal advice in this matter. The Board voted and Motion carried.**

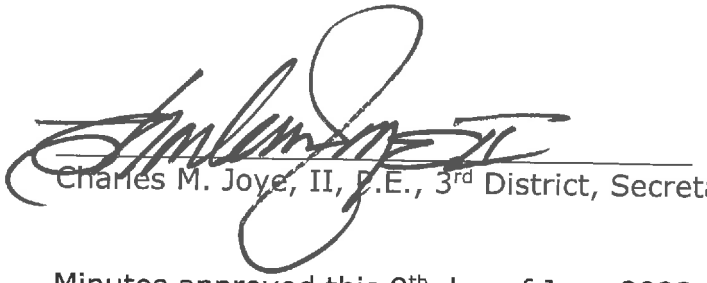
Chairman Bolchoz announced the Board was back in public session and while in Executive Session, no actions were taken.

After further discussion, **Mr. Lee moved, seconded by Mr. Kinney to approve the staff decision with the addition of a special condition to require submission of a sediment sampling plan for Department approval, and if standards approved by Department staff are exceeded, appropriate BMPs and steps are taken to mitigate related risks. The Board voted and the Motion carried.**

Being no further business, Chairman Bolchoz adjourned the meeting.

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

Respectfully submitted,



Charles M. Joye, II, P.E., 3rd District, Secretary

Minutes approved this 9th day of June 2022.

ATTEST:

Robert Bolchoz, Chairman

Attachments

0-1 Agenda
1-1 Minutes of April 7, 2022 meeting
3-1 Administrative Orders and Consent Orders issued by Healthcare Quality
4-1 Administrative Orders and Consent Orders issued by Environmental Affairs
5-1 Request for Placement of Daridorexant in Schedule IV for Controlled Substances in South Carolina
6-1 Request for Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino etonitazene, and Protonitazene in Schedule I for Controlled Substances in South Carolina
7-1 Final Review Conference- Docket No. 22-RFR-12, The Red Brick Pizza. Issuance of Permit Suspension and Cease and Desist Order, Permit No. 15-206-00758, Colleton County
7-2 Department PowerPoint
8-1 Final Review Conference- Docket No. 22-RFR-11, Tom Rowland, Point Farm MB, Inc. Issuance of a critical area permit and coastal zone consistency certification for impacting tidelands critical areas on and adjacent to the North Edisto River and Leadenwah Creek at Point Farm Road, Wadmalaw Island, Charleston County. Permit No. OCRM03332
8-2 Department PowerPoint
8-3 Requestors PowerPoint
8-4 Applicant PowerPoint