

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. Morris E. Brown, III, MD, FAAFP Robert R. Morgan, Jr., MD, MBA

Minutes of the July 15, 2021, meeting of the South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, July 15, 2021, 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) This meeting was rescheduled from July 8, 2021 due to inclement weather.

The following members were in attendance:

Mark Elam, Chairman Morris E. Brown, III, MD, 6th District

In attendance virtually: Jim P. Creel, Jr., Vice-Chairman, 7th District J.B. (Sonny) Kinney, 1st District Seema Shrivastava-Patel, 2nd District Charles M. Joye, II, P.E., 3rd District Robert Morgan, MD, 4th District

Not in attendance: Richard V. Lee, Jr., 5th District

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

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 June 10, 2021 meeting (Attachment 1-1)

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

Item 2: Agency Affairs

Dr. Edward Simmer, Director, updated the Board on,

- COVID 19 surge in cases;
- COVID 19 vaccination;
- Nursing home visitation reporting;
- Plans for increasing service to underserved communities;
- Hurricane Preparedness;
- 2021-2022 Budget;
- Outfall channels.

After discussion, the Board accepted this as information.

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

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, three (3) Consent Orders with assessed civil penalties totaling \$18,400.00, thirty-two (32) Notices of Violation and Civil Penalty totaling \$13,600.00 in assessed civil penalties, and no Administrative Orders were issued.

After discussion, the Board accepted this item as information.

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

Ms. Rebecca Sproles, Liaison, Environmental Affairs, stated that for this reporting period, twenty-five (25) Consent Orders with assessed civil penalties totaling \$67,510.00 and five (5) Administrative Order with assessed civil penalties totaling \$32,625.00 were issued.

After discussion, the Board accepted this item as information.

Item 5: Continuation of Public Hearing for Proposed Designation of Santee-Lynches Capacity Use Area for Chesterfield, Clarendon, Kershaw, Lee, Richland, and Sumter Counties: S.C. Code of Laws, Title 49, Chapter 5, Groundwater Use and Reporting Act

Mr. Alex Butler, Manager, Water Quality Permitting, Underground Injection Control, presented this item to the Board.

Pursuant to S.C. Code Section 49-5-60(A), the Board of the Department of Health and Environmental Control (Department) is directed to designate Capacity Use Areas where excessive groundwater withdrawal presents potential adverse effects to the natural resources or poses a threat to public health, safety, or economic welfare or where conditions pose a significant threat to the long-term integrity of a groundwater source.

49-5-60 (A) states: "In the State where excessive groundwater withdrawal presents potential adverse effects to the natural resources or poses a threat to public health, safety, or economic welfare or where conditions pose a significant threat to the long-term integrity of a groundwater source, including salt water intrusion, the board, after notice and public hearing, in accordance with the Administrative Procedures Act, shall designate a capacity use area. The department, local government authorities, other government agencies, or groundwater withdrawers may initiate the capacity use area designation process. The notice and public hearing must be conducted such that local government authorities, groundwater withdrawers, or the general public may provide comments concerning the capacity use area designation process. A capacity use area must be designated by the board based on scientific studies and evaluation of groundwater resources and may or may not conform to political boundaries."

The Department proposed to designate Chesterfield, Clarendon, Kershaw, Lee, Richland, and Sumter Counties as the Santee-Lynches Capacity Use Area (SLCUA). The Department completed an initial assessment of the groundwater conditions in the area and determined that there is a risk to public health, safety and economic welfare from excessive groundwater withdrawal. Additionally, because large portions of the recharge areas for the primary aquifers of the coastal plain exist in the SLCUA, failure to manage groundwater withdrawals pose a significant long-term threat to the long-term integrity of the groundwater source.

The Department engaged with stakeholders to receive feedback on the proposed SLCUA. Two virtual public meetings were held on January 5, 2021 and January 12, 2021. Additionally, the meetings were recorded and placed on the Department website for public viewing.

A Notice of General Public Interest was published in the State Register on March 26, 2021.

The Board opened the public hearing regarding the proposed designation on June 10, 2021. The Board passed a motion closing the verbal comment period, carrying over the public hearing to the next Board meeting, and opening a two-week period for written comments.

The written comments received were provided to the Board and the public hearing was closed.

Department staff requested the Board designate Chesterfield, Clarendon, Kershaw, Lee, Richland, and Sumter Counties as the Santee-Lynches Capacity Use Area.

After discussion, Mr. Creel moved, seconded by Dr. Brown, that the Board designate Santee-Lynches as a capacity use area to include the following counties: Chesterfield, Clarendon, Kershaw, Lee, Richland, and Sumter. The Board voted and Motion carried.

<u>Item 6: Request for Placement of 4F-MDMB-BINACA in Schedule I for Controlled Substances in South Carolina</u>

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

The Drug Enforcement Administration ("DEA") is establishing a specific listing and Administration Controlled Substances Code Number (drug code) for 4F-MDMB-BINACA (also known as 4F-MDMB-BUTINACA or methyl 2-(1- (4-fluorobutyl)-1H-indazole-3- carboxamido)-3,3-dimethylbutanoate) in schedule I of the Controlled Substances Act (CSA). Although 4F-MDMB- BINACA is not specifically listed in schedule I of the CSA with its own unique drug code, it has been controlled in the United States since April 2017 as a positional isomer of 5F-AMB, a schedule I hallucinogen. Effective June 22, 2021, DEA is simply amending the schedule I hallucinogenic substances list in its regulations to separately include 4F- MDMB-BINACA, Federal Register, Volume 86, Number 117, pages 32633-32635; https://https://www.govinfo.gov/content/pkg/FR-2021-06-22/pdf/2021-13040.pdf.

This rule does not affect the continuing status of 4F– MDMB–BINACA as a schedule I controlled substance in any way. This action, as an administrative matter, merely establishes a separate, specific listing for 4F–MDMB–BINACA in schedule I of the CSA and assigns a DEA controlled substances code number (drug code) for the substance. This action will allow DEA to establish an aggregate production quota and grant individual manufacturing and procurement quotas to DEA-registered manufacturers of 4F–MDMB–BINACA, who had previously been granted individual quotas for such purposes under the drug code for 5F–AMB.

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing 4F-MDMB-BINACA in Schedule I in schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(D) of the South Carolina Controlled Substances Act to include:

() methyl 2-(1- (4-fluorobutyl)-1H-indazole-3- carboxamido)-3,3-dimethylbutanoate).

After discussion, Mr. Kinney moved, seconded by Mr. Creel, that the Board designate 4F-MDMB-BINACA and the additional substances named in the DEA Notice published in the Federal Register on June 22, 2021 and amend Section 44-53-190 (D) of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.

Item 7: Request for Placement of para-Methoxymethamphetamine in Schedule I for Controlled Substances in South Carolina

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

Para-Methoxymethamphetamine ("PMMA") is a substituted phenethylamine and shares structural similarity to methamphetamine, a schedule II controlled substance, and para-methoxyamphetamine (PMA), a schedule I controlled substance. PMMA shares a similar pharmacological profile with 3,4- methylenedioxymethamphetamine ("MDMA" or ecstasy), a schedule I controlled substance with high potential for abuse. Data obtained from preclinical studies show that, similar to MDMA, PMMA's effects are mediated by monoaminergic (dopamine, norepinephrine, and serotonin) transmission, mostly via activation of the serotonergic system. In animals, PMMA mimics MDMA in producing discriminative stimulus effect, which is indicative of similar subjective effects. Law enforcement has encountered PMMA on the recreational drug market where it is sold as "ecstasy," either alone or in combination with MDMA or PMA for oral consumption. For many years, PMMA has been involved in nonfatal and fatal overdoses, primarily in Europe. PMMA has no accepted medical use in treatment in the United States. In March 2016, the Commission on Narcotic Drugs ("CND") voted to place PMMA in Schedule I of the 1971 Convention (CND Dec/59/3) during its 59th Session due to its dependence and abuse potential.

On December 18, 2018, Health and Human Services ("HHS") provided to DEA a scientific and medical evaluation and scheduling recommendation for PMMA. DEA reviewed HHS' evaluation and recommendation for schedule I placement, and all other relevant data, pursuant to 21 U.S.C. 811(b) and (c), and conducted its own analysis under the eight factors stipulated in 21 U.S.C. 811(c). DEA found, under 21 U.S.C. 812(b)(1), that this substance warrants control in schedule I.

After consideration of the scientific and medical evaluation and accompanying recommendation of HHS, and after its own eight-factor evaluation, DEA finds that these facts and all other relevant data constitute substantial evidence of the potential for abuse of PMMA. DEA is permanently scheduling PMMA as a controlled substance under the CSA. The CSA establishes five schedules of controlled substances known as schedules I, II, III, IV, and V. The CSA also specifies the findings required to place a drug or other substance in any particular schedule. 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 other available data, the Acting Administrator of DEA (Acting Administrator), pursuant to 21 U.S.C. 811(a) and 812(b)(1), finds that:

1) The Drug or Substance Has a High Potential for Abuse

PMMA has a mechanism of action similar to that of MDMA, a schedule I controlled substance. Similar to MDMA, PMMA increases levels of monoamines, specifically DA and 5–HT, in the brain reward circuitry. Data from animal studies demonstrate that PMMA fully substitutes for the discriminative stimulus effect of MDMA, which is indicative of similar subjective effects. Although there is currently no data that has directly assessed the psychological or physiological dependence liability of PMMA, its pharmacological similarities to MDMA suggest it likely has low physical dependence liability. Evidence demonstrates that users of PMMA are often seeking MDMA, which may be mixed with PMMA. PMMA shares a pharmacological mechanism of action and psychoactive effects similar to the schedule I controlled substance MDMA and therefore has a high potential for abuse.

2) The Drug or Substance Has No Currently Accepted Medical Use in Treatment in the United States

According to HHS, the Food and Drug Administration ("FDA") has not approved any marketing application for a drug product containing PMMA for any indication. In addition, there are no clinical studies or petitioners that have claimed an accepted medical use of PMMA in the United States. Thus, PMMA has no currently accepted medical use in treatment in the United States

3) There is a Lack of Accepted Safety for Use of the Drug or Substance Under Medical Supervision

The safety of PMMA for use under medical supervision has not been determined because it has no approved medical use in treatment in the United States and has not been investigated as a new drug. Therefore, there is a lack of accepted safety for use of PMMA under medical supervision. Based on these findings, the Acting Administrator concludes that PMMA as well as its salts, isomers, and salts of isomers whenever the existence of such isomers and salts is possible within the specific chemical designation warrants control in schedule I of the CSA. 21 U.S.C. 812(b)(1).

Pursuant to S.C. Code Section 44-53-160(C), the Department recommends placing 1-(4methoxyphenyl)-N-methylpropan-2-(paramethoxymethamphetamine) in Schedule I in the same manner as the federal Drug Enforcement Administration. The listing includes its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation to schedule I for controlled substances in South Carolina and the amendment of Section 44-53-190(D) of the South Carolina Controlled Substances Act to include:

() 1-(4-methoxyphenyl)-N-methylpropan-2-amine (other names: paramethoxymethamphetamine, PMMA).

After discussion, Dr. Morgan moved, seconded by Ms. Shrivastava-Patel, that the Board designate para-Methoxymethamphetamine and the additional substances named in the DEA Notice published in the Federal Register on June 25, 2021 and amend Section 44-53-190 (D) of the S.C. Controlled Substances Act for consistency. The Board voted and Motion carried.

<u>Item 8: Appointment of Hospital Infections Disclosure Act (HIDA) Advisory</u> Committee Member

Mr. Abdoulaye Diedhiou, DADE Division Director, Bureau of Communicable Disease Prevention and Control, presented this item to the Board.

The APIC Palmetto has five (5) representatives on the Hospital Infections Disclosure Act (HIDA). Two (2) positions are being vacated and APIC Palmetto has requested to fill one of those positions with Michelle Bushey. A copy of Ms. Bushey's resume was provided to the Board for review.

After discussion, Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to approve the appointment of Michelle Bushey as APIC representative on the Hospital Infections Disclosure Act Advisory Committee. The Board voted and Motion carried.

<u>Item 9: Appointment of Hospital Infections Disclosure Act (HIDA) Advisory</u> <u>Committee Member</u>

Mr. Abdoulaye Diedhiou, DADE Division Director, Bureau of Communicable Disease Prevention and Control, presented this item to the Board.

The APIC Palmetto has five (5) representatives on the Hospital Infections Disclosure Act (HIDA). Two (2) positions are being vacated and APIC Palmetto has requested to fill one of those positions with Scott Bernshausen. A copy of Mr. Bernshausen's resume was provided to the Board for review.

After discussion, Mr. Kinney moved, seconded by Mr. Creel, to approve the appointment of Scott Bernshausen as APIC representative on the Hospital Infections Disclosure Act Advisory Committee. The Board voted and Motion carried.

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 12th day of August 2021.

ATTEST:

Mark R. Elam, Chairman

Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 Minutes of May 13, 2021 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 Public Hearing for Proposed Designation of Santee-Lynches Capacity Use Area for Chesterfield, Clarendon, Kershaw, Lee, Richland, and Sumter Counties: S.C. Code of Laws, Title 49, Chapter 5, Groundwater Use and Reporting Act
- 5-2 Public Hearing Sign Up Sheet
- 5-3 Verbatim transcript of public hearing
- 6-1 Request for Placement of 4F–MDMB–BINACA in Schedule I for Controlled Substances in South Carolina
- 7-1 Request for Placement of para-Methoxymethamphetamine in Schedule I for Controlled Substances in South Carolina