



**Board:**  
Mark R. Elam, Chairman  
Seema Shrivastava-Patel  
Jim P. Creel, Jr., Vice-Chairman  
Richard V. Lee, Jr.  
Charles M. Joye, II, P.E., Secretary  
Alex A. Singleton  
J.B. (Sonny) Kinney  
Robert R. Morgan, Jr., MD, MBA

## **Minutes of the October 8, 2020, meeting of the South Carolina Board of Health and Environmental Control**

The South Carolina Board of Health and Environmental Control met on Thursday, October 8, 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:

Mark Elam, Chairman  
J.B. (Sonny) Kinney, 1<sup>st</sup> District  
Seema Shrivastava-Patel, 2<sup>nd</sup> District  
Robert Morgan, MD, 4<sup>th</sup> District

In attendance via telephone  
Jim P. Creel, Jr., Vice-Chairman  
Charles M. Joye, II, P.E., 3<sup>rd</sup> District  
Richard V. Lee, Jr., 5<sup>th</sup> District  
Alex A. Singleton, 6<sup>th</sup> District

Also, in attendance were W. Marshall Taylor, Acting Director, Rupinderjit S. Grewal, Legal Counsel; M. Denise Crawford, Clerk; and Department staff. The meeting was also available via Livestream. (Attachment 0-2)

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 September 10, 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 Orders and Consent Orders issued by Healthcare Quality** (Attachment 2-1)

Ms. Bentley White, Director of Policy and Communications, Healthcare Quality, stated that for this reporting period, one (1) Administrative Order with no assessed civil penalty and one (1) Consent Order with an assessed civil penalty totaling \$1,885.00 have been issued.

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, forty-three (43) Consent Orders with assessed civil penalties totaling \$55,430.00 and eight (8) Administrative Orders with no assessed civil penalties have been issued.

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

**Item 4: Notice of Proposed Regulation amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals** (Attachment 4-1)

Ms. Jana White, Manager, Solid Waste Planning Section, Environmental Affairs, presented this item to the Board.

The Bureau of Land and Waste Management ("Bureau") proposed the Notice of Proposed Regulation amending R.61-107.4, *Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals*, for publication in the October 23, 2020, *South Carolina State Register* ("State Register"). Legal authority resides in the South Carolina Solid Waste Policy and Management Act, S.C. Code Sections 44-96-10 *et seq.*, which requires the Department to promulgate regulations establishing standards for the management of yard trash and land-clearing debris and production of compost. The Administrative Procedures Act, S.C. Code Section 1-23-120(A), requires General Assembly review of these proposed amendments.

Pursuant to S.C. Code Sections 44-96-10 *et seq.*, the Department must establish standards for the management of yard trash and land-clearing debris and production of compost. The proposed amendments improve environmental protection, ensure adequate, but not burdensome, financial assurance to close facilities that cease operating, provide clarity for permit exemptions, update operational criteria, and correct typographical and other similar errors.

The Department had a Notice of Drafting published in the May 22, 2020, *State Register*. A copy of the Notice of Drafting appears herein as Attachment B. The Department received public comments from two parties by the June 23, 2020, close of the public comment period. Attachment C presents a summary of these public comments received and Department responses.

The Bureau conducted a stakeholder engagement meeting was conducted virtually on August 24, 2020. Participants included representatives of the compost industry, the waste industry, environmental organizations, and city and county government. Additionally, the Bureau provided representatives from Clemson University's Department of Plant Industry and the U.S. Department of Agriculture copies of the draft and invited to participate and/or comment. The Bureau also invited parties that commented on the Notice of Drafting to participate in this meeting.

Department staff conducted an internal review of the proposed amendments on September 3, 2020.

The Bureau requested the Board grant approval of the Notice of Proposed Regulation for publication in the October 23, 2020, *State Register*.

After discussion, **Mr. Kinney moved, seconded by Ms. Shrivastava-Patel, to grant approval to publish the Notice of Proposed Regulation amending Regulation 61-107.4, *Solid Waste Management: Compost and Mulch Production from Land-Clearing Debris, Yard Trimmings and Organic Residuals*, 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 Crotonyl Fentanyl into Schedule I for Controlled Substances**

(Attachment 5-1)

Ms. Christie Frick, Prescription Monitoring Program Director, 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 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 shall be 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.

South Carolina 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 Chairmen 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.

The Acting Administrator of the Drug Enforcement Administration ("DEA") issued a final order to place crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, in schedule I of the Controlled Substances Act ("federal CSA"). This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export,

engage in research or conduct instructional activities with, or possess), or propose to handle crotonyl fentanyl. The federal order to schedule crotonyl fentanyl became effective October 2, 2020, *Federal Register*, Volume 85, Number 192, pages 62215-62218; <https://www.govinfo.gov/content/pkg/FR-2020-10-02/pdf/2020-19305.pdf>.

The United States is a party to the 1961 United Nations Single Convention on Narcotic Drugs ("Single Convention"), March 30, 1961, 18 U.S.T. Article 3, paragraph 7 of the Single Convention requires that if the Commission on Narcotic Drugs ("Commission") adds a substance to one of the schedules of such Convention, and the United States receives notification of such scheduling decision from the Secretary-General of the United Nations ("Secretary-General"), the United States, as a signatory Member State, is obligated to control the substance under its national drug control legislation. Under 21 U.S.C. 811(d)(1) of the federal CSA, if control of a substance is required "by United States' obligations under international treaties, conventions, or protocols, in effect on October 27, 1970," the Attorney General must issue an order permanently controlling such drug under the schedule he deems most appropriate to carry out such obligations, without regard to the findings required by 21 U.S.C. 811(a) or 812(b), and without regard to the procedures prescribed by 21 U.S.C. 811(a) and (b).

## 1) Background

The DEA issued a temporary scheduling order on February 6, 2018, placing fentanyl-related substances, as defined in the order, in schedule I of the CSA. The order was based on findings by the former Acting Administrator that the temporary scheduling of this class of substances was necessary to avoid an imminent hazard to the public safety. On April 19, 2019, in the *Federal Register*, the DEA provided the chemical name for crotonyl fentanyl, along with four other substances, identifying how these individual substances met the definition for fentanyl-related substances, and, as such, were already covered by the February 2018 temporary order. Regarding crotonyl fentanyl specifically, this substance was not otherwise controlled in any schedule and is structurally related to fentanyl by the replacement of the N-propionyl group by another acyl group. Congress extended the temporary control of fentanyl-related substances on February 6, 2020.

## 2) Scope and Significance of Abuse

Crotonyl fentanyl has a pharmacological profile similar to morphine, fentanyl, and other synthetic opioids that act as m-opioid receptor agonists. For this reason, crotonyl fentanyl is abused for its opioid-like effects. Law enforcement reports in the United States demonstrate the illicit use and distribution of this substance, which are similar to that of heroin and prescription opioid analgesics. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by other federal, state, and local forensic laboratories across the country. According to NFLIS, there have been 143 reports containing crotonyl fentanyl since it was first reported in June 2017.

In order to meet the United States' obligations under the Single Convention and because crotonyl fentanyl has no currently accepted medical use in treatment in the United States, the Acting Administrator has determined that crotonyl fentanyl, including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible, should remain in schedule I of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide), including its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers 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 to include: ( ) Crotonyl fentanyl ((E)-N-(1-phenethylpiperidin-4-yl)-N-phenylbut-2-enamide)

After discussion, **Mr. Creel moved, seconded by Mr. Kinney, to designate the additional substances named in the DEA Notice published in the Federal Register on October 2, 2020, and amend Section 44-53-190 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.**

**Item 6: Placement of Remimazolam into Schedule IV for Controlled Substances**  
(Attachment 6-1)

Ms. Christie Frick, Prescription Monitoring Program Director, 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 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 shall be 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.

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 Chairmen 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.

The United States Food and Drug Administration ("FDA") approved a new drug application for BYFAVO (remimazolam) for intravenous use on July 2, 2020. Remimazolam is chemically known as 4H-imidazol[1,2-a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-

pyridinyl)-(4S)-methyl ester, benzenesulfonate (1:1) and also, methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid. The Department of Health and Human Services ("HHS") provided the Drug Enforcement Administration ("DEA") with a scheduling recommendation to place remimazolam and its salts in schedule IV of the Controlled Substances Act ("federal CSA"). In accordance with the federal CSA, as amended by the Improving Regulatory Transparency for New Medical Therapies Act, the DEA is hereby issuing an interim final rule placing remimazolam, 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 CSA, effective October 6, 2020. *Federal Register*, Volume 85, Number 194, pages 63014-63019; <https://www.govinfo.gov/content/pkg/FR-2020-10-06/pdf/2020-19313.pdf>.

Remimazolam (4H-imidazol[1,2-a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)-methyl ester, benzenesulfonate (1:1) or methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2-a][1,4]benzodiazepin-4-yl]propanoate benzenesulfonic acid), is a new molecular entity with Central Nervous System ("CNS") depressant properties. Remimazolam is an agonist at gamma-aminobutyric acid subtype A ("GABA") receptors. On April 5, 2019, Cosmo Technologies, Ltd. ("Sponsor") submitted a new drug application ("NDA") for BYFAVO (remimazolam) to the FDA with a proposed dose of 5.0 mg intravenous ("i.v.") with supplemental doses of 2.6 mg i.v.. The DEA received notification on July 2, 2020 that FDA, on the same date, approved the NDA for BYFAVO (remimazolam), under section 505(c) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), to be used as an i.v. treatment for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. In January 2020, remimazolam was approved for marketing in Japan for general anesthesia.

On July 10, 2020, DEA received from HHS a scientific and medical evaluation, dated April 15, 2020, entitled "Basis for the Recommendation to Control Remimazolam and its Salts in Schedule IV of the Controlled Substances Act" and a scheduling recommendation. This document contained an eight-factor analysis of the abuse potential, legitimate medical use, and dependence liability of remimazolam, along with a recommendation from HHS to control remimazolam and its salts under schedule IV of the CSA. 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 remimazolam meets the 21 U.S.C. 812(b)(4) criteria for placement in schedule IV of 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 Acting Administrator of DEA, pursuant to 21 U.S.C. 812(b)(4), finds that:

- 1) Remimazolam Has a Low Potential for Abuse Relative to the Drugs or Other Substances in Schedule III. Remimazolam, similar to that of the schedule IV drug midazolam, is an agonist at GABA receptors. Remimazolam produced depressant effects in general behavior assessments, and generalized to midazolam (schedule IV), in a drug discrimination study in animals, demonstrating it has GABA receptor agonist properties. In a human abuse potential study, remimazolam at the therapeutic and supra-therapeutic doses produced positive subjective responses such as Drug Liking, Overall Drug Liking, Good Drug Effects, and Take Drug Again similar to those of midazolam (schedule IV) and significantly higher than placebo. Furthermore, data from other clinical studies show that remimazolam produced abuse-related adverse events,

namely euphoria and somnolence. Because remimazolam is similar to midazolam (schedule IV) in its abuse potential, remimazolam has a lower potential for abuse relative to the drugs or other substances in schedule III.

- 2) Remimazolam Has a Currently Accepted Medical Use in the United States. FDA recently approved the NDA for BYFAVO (remimazolam) injection for use in the induction and maintenance of procedural sedation in adults undergoing procedures lasting thirty (30) minutes or less. Thus, remimazolam has a currently accepted medical use for treatment in the United States.
- 3) Remimazolam May Lead to Limited Physical Dependence or Psychological Dependence Relative to the Drugs or Other Substances in Schedule III. Remimazolam shares a similar pharmacology profile with benzodiazepine drugs. Abrupt discontinuation of benzodiazepines is associated with withdrawal symptoms. Remimazolam produced withdrawal symptoms after abrupt discontinuation in monkeys, indicative of physical dependence, similar to that of benzodiazepines. In addition, remimazolam produced positive subjective responses and euphoria-related adverse events in a human abuse potential study. It is likely that remimazolam can produce psychic dependence similar to midazolam. Thus, abuse of remimazolam may lead to limited physical or psychological dependence relative to the drugs or other substances in schedule III of the CSA.

Pursuant to South Carolina Code Section 44-53-160(C), the Department recommends the addition of remimazolam to Schedule IV for controlled substances in South Carolina and the amendment of Section 44-53-250(a) of the South Carolina Code of Laws to include: ( ) Remimazolam (4H-imidazo[1,2- a][1,4]benzodiazepine-4-propionic acid, 8-bromo-1-methyl-6-(2-pyridinyl)-(4S)- methyl ester, benzenesulfonate (1:1) or methyl 3-[(4S)-8-bromo-1-methyl-6-pyridin-2-yl-4H-imidazo[1,2-a][1,4]benzodiazepin-4yl]propanoate benzenesulfonic acid).

After discussion, **Dr. Morgan moved, seconded by Ms. Shrivastava-Patel, to designate the additional substances named in DEA Notice published in the Federal Register on October 6, 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.**

#### **Item 7: Agency Affairs**

Dr. Brannon Traxler, Deputy Director of Public Health, provided an update on the COVID 19 (Coronavirus).

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

Dr. Brannon Traxler, Deputy Director of Public Health, provided an update on the upcoming flu season.

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

W. Marshall Taylor, Jr., Acting Director, provided an update to the Board on the agency response to COVID 19, recognized Department staff for their continued efforts to maintain normal operations, and the Department's coordination with its partners during the pandemic.

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

W. Marshall Taylor, Jr., Acting Director, recognized Myra Reece, Deputy Director for Environmental Affairs, appointment to serve as the Secretary-Treasurer for the Environmental Council of States.

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

**Executive Session**

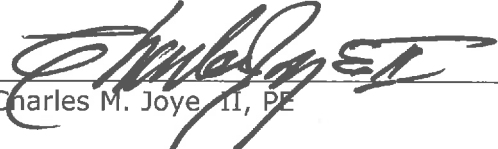
**Mr. Kinney made a motion that the Board go into Executive Session pursuant to SC Code Section 30-4-70(A)(1) and (A)(2) to discuss a personnel matter and to obtain legal advice. Ms. Shrivastava-Patel seconded the motion and the motion carried unanimously.**

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

Being no further business, the meeting was adjourned.

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

Respectfully submitted,

  
Charles M. Joye II, PE

Minutes approved this 12<sup>th</sup> day of November 2020.

ATTEST:

  
Mark R. Elam, Chairman



Attachments

- 0-1 Agenda
- 0-2 Sign in Sheet
- 1-1 September 10, 2020 Minutes
- 2-1 Administrative Orders and Consent Orders issued by Healthcare Quality
- 3-1 Administrative Orders and Consent Orders issued by Environmental Affairs
- 4-1 Notice of Proposed Regulation amending R.61-107.4, Solid Waste Management: Compost and Mulch Production from Land-clearing Debris, Yard Trimmings and Organic Residuals
- 5-1 Placement of Crotonyl Fentanyl into Schedule I for Controlled Substances
- 6-1 Placement of Remimazolam into Schedule IV for Controlled Substances 7-1