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Promoting and protecting the health of the public and the environment
South Carolina Board of Health and Environmental Control

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BOARD:
R. Kenyon Wells
Charles M. Joye II, P.E.
L. Clarence Batts, Jr.
David W. Gillespie, MD
William Lee Hewitt, III

South Carolina Board of Health and Environmental Control

June 9, 2016

The South Carolina Board of Health and Environmental Control met on Thursday, June 9, 2016, at 10:00 a.m. in the Board Room of the South Carolina Department of Health and Environmental Control, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance:

Allen Amsler, Chairman, Member-at-Large
Ann B. Kirol, DDS, Secretary, 5th District
David W. Gillespie, MD, 6th District

In attendance via phone:

Mark S. Lutz, Vice-Chairman, 1st District
Charles M. Joye, II, P.E., 3rd District
L. Clarence Batts, 4th District
William Lee Hewitt, III, 7th District

Absent:

R. Kenyon Wells, 2nd District

Also in attendance were W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and members of the public. (Attachment 0-2)

Chairman Amsler 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 Amsler welcomed Dr. Gillespie to the Board representing Congressional District 6.

Item 1: Minutes of May 12, 2016 meeting (Attachment 1-1)

Mr. Hewitt moved, seconded by Mr. Batts, to approve the minutes as presented for the May 12, 2016 meeting. The Board voted and Motion carried.

Item 2: Administrative and Consent Orders issued by Environmental Affairs (Attachment 2-1)

Ms. Robin Stephens, Compliance Assistance and Enforcement, Environmental Affairs, stated two (2) Administrative Orders and fifty-five (55) Consent Orders had been issued with total penalties of \$82,834.

The Board accepted this item as information.

Item 3: Administrative Orders, Consent Orders and Sanction Letters issued by Health Regulation (Attachment 3-1)

Ms. Bentley White, Health Regulation Program Manager, stated three (3) Consent Orders and one (1) Emergency Order had been issued with total penalties of \$36,500.

The Board accepted this item as information.

Item 4: Proposed Amendment of Regulation 61-79, Hazardous Waste Management Regulations, Legislative Review required (Attachment 4-1)

Mr. David Scaturo, Director, Division of Hazardous Waste Management, presented this item to the Board.

The Department proposed to amend R.61-79 as follows:

- to adopt the “Conditional Exclusion for Carbon Dioxide (CO₂) Streams in Geologic Sequestration Activities,” published on January 3, 2014 at 79 FR 350-364;
- to amend R.61-79 to adopt the “Revisions to the Definition of Solid Waste,” published on January 13, 2015 at 80 FR 1694-1814.

After discussion, Dr. Kirol moved, seconded by Mr. Batts, to grant approval to publish Notice of Proposed Regulation 61-79, Hazardous Waste Management Regulations, 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: Proposed Amendment of Regulation 61-62, Air Pollution Control Regulations and Standards, and the South Carolina Air Quality Implementation Plan (“SIP”), Legislative Review is not required (Attachment 5-1)

Mr. Robbie Brown, Director, Division of Air Assessment and Regulations, presented this item to the Board.

Pursuant to the South Carolina Pollution Control Act, along with the federal Clean Air Act, the Department must ensure national primary and secondary ambient air quality standards are achieved and maintained in South Carolina. No state may adopt or enforce an emission standard or limitation less stringent than these federal standards or limitations.

The United States Environmental Protection Agency (“EPA”) promulgates amendments to the Code of Federal Regulations (“CFR”) throughout each calendar year. Recent federal amendments include clarification, guidance and technical revisions to SIP requirements, New Source Performance Standards (“NSPS”), and federal National Emission Standards for Hazardous Air Pollutants (“NESHAP”) for Source Categories.

The Department proposed to amend Regulation 61-62 as follows:

- 61-62.1, Section III, Emissions Inventory and Emissions Statements; Regulation 61-62.60, South Carolina Designated Facility Plan and New Source Performance Standards; Regulation 61-62.63, National Emission Standards for Hazardous Air Pollutants (NESHAP) for Source Categories; Regulation 61-62.5, Standard No. 2, Ambient Air Quality Standards; and the SIP, to adopt the federal amendments to these standards put forth from January 1, 2015, through December 31, 2015.
- 61-62.1, Section II, Permit Requirements; Regulation 61-62.5, Standard No.1, Emissions From Fuel Burning Operations; and Regulation 61-62.5, Standard No. 4, Emissions from Process Industries, to address periods of excess emissions during startup, shutdown, or malfunction (“SSM”) events as required by the EPA in response to a national petition for rulemaking and to address a finding of substantial inadequacy (referred to as a “SIP call”) (80 FR 33840, June 12, 2015).
- other changes to Regulation 61-62 that include corrections for internal consistency, clarification, reference, punctuation, codification, formatting, and spelling to improve the overall text of Regulation 61-62 as necessary.

After discussion, Mr. Batts moved, seconded by Dr. Kirol, to grant approval to publish a Notice of Proposed Regulation 61-62, Air Pollution Control Regulations and South Carolina Air Quality Implementation Plan, 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 6: Placement of Brivaracetam into Schedule V for Controlled Substances (Attachment 6-1)

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

Controlled substances are governed by the Controlled Substances Act (CSA), found at Title 44, Chapter 53, of the S.C. Code of Laws. Section 44-53-160 is titled “Manner in which changes in schedule of controlled substances shall be made.” Pursuant to § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule V substances are listed in § 44-53-270. 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.

The U.S. Department of Justice, Drug Enforcement Administration (DEA), published on May 12, 2016, its interim final rule scheduling the substance brivaracetam ((2S)-2-[(4R)-2-oxo-4-

propylpyrrolidin-1-yl] butanamide) (also referred to as BRV; UCB-34714; Briviact), including its salts, into schedule V of the federal Controlled Substances Act (CSA), effective immediately. This action is based on a finding by the Administrator that the placement of brivaracetam into schedule V of the federal CSA is necessary because it has a potential for abuse similar to other schedule V substances.

Brivaracetam is a new molecular entity, not yet marketed in the U.S. or any other countries, having central nervous system depressant properties. On March 28, 2015, the DEA received notice that the U.S. Department of Health and Human Services and the U.S. Food and Drug Administration had approved the use of brivaracetam in the treatment of epilepsy. Upon conducting its own review, the DEA concluded that brivaracetam met the criteria for placement in schedule V of the federal CSA because a review of available data showed it had fewer negative effects than substances in schedule IV, and it had an abuse potential similar to other schedule V substances.

When determining whether a substance should be placed into Schedule IV of the S.C. Controlled Substances Act, Section 44-53-260 of the S.C. Code of Laws requires “the Department shall place a substance in Schedule V if it finds that: (a) It has a low potential for abuse relative to the substances listed in Schedule IV; (b) It has a currently accepted medical use in treatment in the United States; and (c) Abuse of the substance may lead to limited physical dependence or psychological dependence relative to the substances listed in Schedule IV.” According to its interim final rule, the DEA has concluded brivaracetam has a potential for abuse similar to other schedule V substances, a currently accepted medical use in the U.S., limited risk of psychological dependence and no apparent risk of physical dependence; therefore, brivaracetam should be placed in schedule V of the federal Controlled Substances Act effective May 12, 2016.

Dr. Kirol moved, seconded by Dr. Gillespie, to designate the additional substances as named in the DEA notice published in the Federal Register on May 12, 2016, 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. Board Scheduling Document to General Assembly (Attachment 6-2)

Item 7: Agency Affairs

No Report

Meeting adjourned.

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

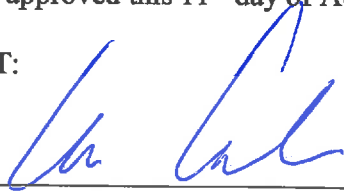
Respectfully submitted,



Ann B. Kirol, DDS, Secretary

Minutes approved this 11th day of August 2016.

ATTEST:



Allen Amsler, Chairman

Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 May 12, 2016 minutes
- 2-1 Administrative and Consent Orders issued by Environmental Affairs
- 3-1 Administrative Orders, Consent Orders and Sanctions issued by Health Regulation
- 4-1 Proposed Amendment of R.61-79, Hazardous Waste Management Regulations
- 5-1 Proposed Amendment of R.61-62, Air Pollution Control Regulations and Standards
- 6-1 Placement of Brivaracetam into Schedule V of SC Controlled Substances
- 6-2 Board Designation Document