



**Board:**  
Allen Amsler, *Chairman*  
Ann B. Kirol, DDS, *Vice Chair*  
L. Clarence Batts, Jr., *Secretary*  
R. Kenyon Wells  
Charles M. Joye II, P.E.  
David W. Gillespie, MD

## **Minutes of the April 5, 2017 meeting of the South Carolina Board of Health and Environmental Control**

The South Carolina Board of Health and Environmental Control met on Wednesday, April 5, 2017, 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, Member-at-Large  
Ann B. Kirol, DDS, Vice Chair, 5th District  
L. Clarence Batts, Secretary, 4th District  
R. Kenyon Wells, 2nd District  
David W. Gillespie, MD, 6th District

Absent:

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

1st District and 7th District seats are currently vacant.

Also in attendance were Catherine E. Heigel, Director, via telephone; W. Marshall Taylor, Jr., General Counsel; Lisa L. Longshore, Clerk; Department staff and members of the public. (Attachment 0-2)  
The meeting was live streamed on the internet.

Chairman Allen 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.

### **Item 1: Minutes of March 9, 2017 meeting** (Attachment 1-1)

***Dr. Kirol moved, seconded by Dr. Gillespie, to approve the minutes as presented for the March 9, 2017, Board meeting. The Board voted and Motion carried.***

### **Item 2: Placement of Dronabinol (Syndros) Into Schedule II SC Controlled Substances** (Attachment 2-1)

Ms. Lisa Thomson, Director, 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 this section, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule II substances are listed in Section 44-53-210. Section 44-53-160(C) provides a process by which DHEC can expeditiously designate substance as a controlled substance if the federal government has so designated.

On July 1, 2016, the U.S. Food and Drug Administration (FDA) approved a new drug application for Syndros, a drug product consisting of dronabinol [(+)-delta-9-tetrahydrocannabinol (delta-9-THC)] oral solution. Thereafter, the Department of Health and Human Services (HHS) provided the Drug Enforcement Administration (DEA) with a scheduling recommendation that would result in Syndros (and other oral solutions containing dronabinol) being placed in schedule II of the Controlled Substances Act (CSA). In accordance with the CSA, as revised by the Improving Regulatory Transparency for New Medical Therapies Act, DEA issued an interim final rule placing FDA-approved products of oral solutions containing dronabinol in schedule II of the CSA. DATES: The effective date of this rulemaking is March 23, 2017. <https://www.gpo.gov/fdsys/pkg/FR-2017-03-23/pdf/2017-05809.pdf>.

After discussion, **Mr. Wells moved seconded by Mr. Batts, to designate the additional substances as named in the DEA Interim Final Rule published in the Federal Register on March 23, 2017, and amend Section 44-53-210 of the S.C. Controlled Substances Act for consistency with the Federal scheduling. The Board voted and Motion carried.** Board Designation Document (Attachment 2-2)

**Item 3: Final Review Conference – Docket No. 17-RFR-12, Keenan Energy Group f/k/a Keenan Oil Co.** (Attachment 3-1)

Chairman Amsler announced the agenda item and then asked Mr. Taylor to introduce the matter.

Sara P. Bazemore represented the Department. (Attachment 3-2)

Keenan Energy Group f/k/a Keenan Oil Co. was represented by W. Thomas Lavender. (Attachment 3-3)

Mr. Mihir Mehta, Mr. Bill Keenan and Mr. Don Siron were sworn in as witnesses in this matter.

After discussion, **Mr. Wells moved, seconded by Dr. Gillespie, to go into Executive Session for the purpose of deliberations and legal advice in this matter. The Board voted and Motion carried.**

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

After further discussion, **Dr. Kirol moved, seconded by Mr. Batts, to uphold the staff decision. The Board voted and Motion carried.**

Chairman Amsler stated a need for an Executive Session for legal advice on GAP Analysis being conducted by the Department. Dr. Kirol moved, seconded by Mr. Wells, to go into Executive Session for legal advice on the Gap Analysis. The Board voted and Motion carried.

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

Dr. Gillespie moved, seconded by Dr. Kirol, to adjourn. The Board voted yes and Chairman Amsler adjourned the meeting.

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

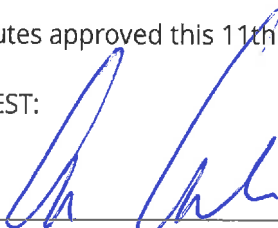
Respectfully submitted,



L. Clarence Batts, Jr., Secretary

Minutes approved this 11th day of May 2017.

ATTEST:



Allen Amsler, Chairman

#### Attachments

- 0-1 Agenda
- 0-2 Attendance Roster
- 1-1 March 9 meeting minutes
- 2-1 Placement of Dronabinol (Syndros) Into Schedule II SC Controlled Substances
- 2-2 Board Designation document
- 3-1 Final Review Conference - Docket No. 17-RFR-12, Keenan Energy Group f/k/a Keenan Oil Co.
- 3-2 Presentation by DHEC
- 3-3 Presentation by Keenan Energy Group