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Catherine B. Templeton, Director
Promoting and protecting the health of the public and the environment

Minutes of the September 25, 2014, conference call meeting of the

South Carolina Board of Health and Environmental Control

The South Carolina Board of Health and Environmental Control met on Thursday, September 25, 2014, via teleconference at 2:30 p.m. in the Board Room at the South Carolina Department of Health and Environmental Control building, 2600 Bull Street, Columbia, South Carolina. (Attachment 0-1)

The following members were in attendance via telephone:

Allen Amsler, Chairman
Member-At-Large

Mark S. Lutz, Vice-Chairman
1st District

R. Kenyon Wells
2nd District

L. Clarence Batts
4th District

Ann B. Kirol, DDS
5th District

William Lee Hewitt, III
7th District

Also in attendance were W. Marshall Taylor, Jr., General Counsel; Lisa Lucas Longshore, Clerk; Department staff. (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.

Item 1: Placement of Suborexant into Schedule IV for Controlled Substances (Attachment 1-1)

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 § 44-53-160, controlled substances are generally designated by the General Assembly, upon recommendation by DHEC. Schedule IV substances are listed in § 44-53-250. 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 August 28, 2014, its final rule placing the substance [(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone (suvorexant), including its salts, isomers, and salts of isomers, into schedule IV of the Controlled Substances Act (CSA), effective on September 29, 2014. F.R. Volume 79, Number 167, pp. 51243-51247; http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/fr0828.htm

Suvorexant ([(7R)-4-(5-chloro-1,3-benzoxazol-2-yl)-7-methyl-1,4-diazepan-1-yl][5-methyl-2-(2H-1,2,3-triazol-2-yl)phenyl]methanone), also known as MK-4305, is a new chemical entity developed for the treatment of insomnia. Suvorexant is a novel, first in class, orexin receptor antagonist with a mechanism of action distinct from any marketed drug. The U.S. Food and Drug Administration (FDA) approved the new drug application for suvorexant on August 13, 2014.

After considering the eight factors in 21 U.S.C. 811(c), including consideration of the substance's abuse potential, legitimate medical use, and dependence liability, the Assistant Secretary of the HHS recommended that suvorexant be controlled in schedule IV of the CSA under 21 U.S.C. 812(b). In response, the DEA conducted its own analysis of the eight factors determinative of control or removal: (1) Its actual or relative potential for abuse; (2) scientific evidence of its pharmacological effect, if known; (3) the state of current scientific knowledge regarding the drug or other substance; (4) its history and current pattern of abuse; (5) the scope, duration, and significant of abuse; (6) what, if any, risk there is to the public health; (7) its psychic or physiological dependence liability; and (8) whether the substance is an immediate precursor of a substance already controlled. The summary of each factor as analyzed by the DEA and the HHS, and as considered by the DEA in this scheduling action, was provided in the proposed rule.

Based on the review of the HHS evaluation and scheduling recommendation and all other relevant data, the DEA found that suvorexant has an abuse potential similar to other schedule IV drugs, including zolpidem (schedule IV). As such, the DEA is scheduling suvorexant as a controlled substance under the CSA.

After discussion, ***Mr. Batts moved, seconded by Dr. Kirol, to adopt the final scheduling of Suborexant as defined in the Board package and Federal Register Volume 79, Number 167, pp. 51243-51247 and amend Section 44-53-250 by adding and designating Suvorexant into Schedule IV of the South Carolina Controlled Substances Act, effective September 29, 2014. The Board voted and Motion carried by a vote of 5-1 with Mr. Wells being the dissenting vote.*** (Attachment 1-2)

Chairman Amsler adjourned the meeting.

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

Respectfully submitted,

Ann B. Kirol, DDS, Secretary

Minutes approved this 9th day of October 2014.

ATTEST:

Allen Amsler, Chairman

Attachments
0-1 Agenda
0-2 Attendance Roster
1-1 Placement of Suborexant into Schedule IV for Controlled Substances
1-2 Board Designation