

TEXAS DEPARTMENT OF STATE HEALTH SERVICES

DAVID L. LAKEY, M.D.
COMMISSIONER

March 7, 2012

ACTION

MEMORANDUM FOR THE COMMISSIONER

THROUGH: Anne Mosher, Point of Contact
Executive Communications and Correspondence

FROM: Kathryn C. Perkins, R.N., M.B.A., Assistant Commissioner
Division for Regulatory Services

SUBJECT: Addition of ezogabine to Schedule V of the Texas schedules of controlled substances

Purpose The Commissioner is required to sign any amendment to the Texas schedules of controlled substances for publication in the *Texas Register*. Please return the signed original to the Drugs and Medical Devices Group (MC 1987).

Background/Summary

Health and Safety Code, Chapter 481, §481.034(g) grants the following authority to the Commissioner as stated: “if a substance is designated, rescheduled, or deleted as a controlled substance under federal law and notice of that fact is given to the commissioner, the commissioner similarly shall control the substance under this chapter.” If you have any questions, please call Karen Tannert, R.Ph., M.P.H., Chief Pharmacist at (512) 834-6755 ext. 2350.

Discussion

The purpose of this law is to allow modifications to the schedules as soon as changes are made to the federal Controlled Substances Act by either the U.S. Congress or the Drug Enforcement Administration. The signature on any such amendment is mandated by law to be that of the Commissioner. This amendment to the schedules follows the federal schedules. The Commissioner does not have the option of changing the schedules on his own volition. Any change to the schedules, made by the Commissioner, requires an 8 step process to increase restrictions. The Commissioner is prohibited by federal law from decreasing those restrictions. The consequences of not signing the amendment as presented would place medical communities and law enforcement into a situation where they would be required to follow federal schedules

that do not match the state schedules, and thus would not know if their actions violate state law. The positive implication of signing this schedule is that both the medical community and law enforcement are assured that Texas follows the federal schedules and that their actions in the state of Texas are lawful.

Recommendation


After signature by the Commissioner, it would be appreciated if the Office of General Counsel would handle the filing with the Secretary of State.

Attachments

Amendment adding ezogabine, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule V

Commissioner's Decision

Approve

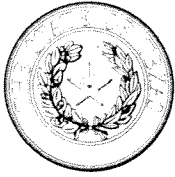
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Disapprove

Modify

Needs More Discussion

Pend for Future Consideration



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DAVID L. LAKEY, M.D.
COMMISSIONER

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The Administrator of the Drug Enforcement Administration (DEA) placed the substance ezogabine including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible, into Schedule V of the federal schedules of controlled substances under the authority of the United States Controlled Substances Act (USCSA) effective December 15, 2011. This final rule was published in the Federal Register Volume 76, Number 241, pages 77895-77899. The Administrator of the DEA has taken this action based on a scheduling recommendation from the Assistant Secretary for Health of the Department of Health and Human Services and on the following:

- (1) Ezogabine has a low potential for abuse relative to the drugs or other substances in Schedule IV. The overall abuse potential of ezogabine is comparable to the Schedule V substances such as pregabalin and lacosamide;
- (2) Ezogabine has a currently accepted medical use in treatment in the United States. Ezogabine was approved for marketing by FDA as an adjunct treatment of partial onset seizures; and
- (3) Abuse of ezogabine may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV.

Pursuant to Section 481.034(g), as amended by the 75th legislature, of the Texas Controlled Substances Act, Health and Safety Code, Chapter 481, at least thirty-one days have expired since notice of the above referenced action was published in the Federal Register; and, in my capacity as Commissioner of the Texas Department of State Health Services, I do hereby order that the substance ezogabine including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible be added to Schedule V Depressants and numbers (1) and (2) be redesignated as (2) and (3).

SCHEDULE V

Schedule V consists of:

- Schedule V narcotics containing non-narcotic active medicinal ingredients

- Schedule V stimulants


- Schedule V depressants

Unless specifically exempted or excluded or unless listed in another schedule, any material, compound, mixture, or preparation, which contains any quantity of the following substances having a depressant effect on the central nervous system, including its salts:

- *(1) Ezogabine including its salts, isomers and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible
- (2) Lacosamide [(R)-2-acetoamido-N-benzyl-3-methoxy-propionamide]; and
- (3) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid].

Changes to the Schedules are designated by an asterisk (*)

Done in Austin, Texas this 23rd day of March, 2012 in witness whereof I hereunto set my hand and seal of office.



David L. Lakey, M.D.
Commissioner

