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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–325F]

Schedules of Controlled Substances: Placement of Lacosamide into Schedule V

AGENCY: Drug Enforcement Administration (DEA), Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the DEA places the substance lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide] and any material, compound, mixture, or preparation which contains any quantity of lacosamide into schedule V of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule V will be applicable to the manufacture, distribution, dispensing, importation and exportation of lacosamide.

DATES: *Effective Date:* This rule is effective June 22, 2009.

FOR FURTHER INFORMATION CONTACT: Christine A. Sannerud, PhD, Chief, Drug and Chemical Evaluation Section, Office of Diversion Control, Drug Enforcement Administration, 8701 Morrissette Drive, Springfield, VA 22152, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Background

On October 28, 2008, the Food and Drug Administration (FDA) approved lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide] for marketing under the trade name Vimpat® for use as an adjunctive therapy in treatment of partial-onset seizures in patients with epilepsy ages 17 years and older.

On December 2, 2008, the Assistant Secretary for Health of the Department of Health and Human Services (DHHS) sent the Administrator of the DEA a scientific and medical evaluation and a letter recommending that lacosamide be placed into schedule V of the CSA. Enclosed with the December 2, 2008, letter was a document prepared by the FDA entitled ''Basis for the Recommendation for Control of Lacosamide in Schedule V of the Controlled Substances Act (CSA).'' The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

Based on the recommendation of the Assistant Secretary for Health and an independent review of the available data by the DEA, the Deputy Administrator of the DEA, in a March 10, 2009, Notice of Proposed Rulemaking (74 FR 10205) proposed placement of lacosamide into schedule V of the CSA. The proposed rule provided an opportunity for all interested persons to submit their comments, objections, or requests for hearing to be received by the DEA on or before April 9, 2009.

Comments Received

DEA received one comment within the comment period in response to the Notice of Proposed Rulemaking. The commenter stated that lack of information and inappropriate comparisons to other drugs precluded the scheduling of lacosamide and suggested that scheduling be postponed for 24 months to collect data.

DEA does not agree. The studies used to assess abuse potential of lacosamide are widely held as the standard methods of evaluation. Behavioral effects of lacosamide in animals and humans were found to be similar to, but transient relative to, those of the schedule IV drugs alprazolam and phenobarbital. Preclinical studies indicated that lacosamide is self-administered at rates higher than saline and partially mimics discriminitive stimulus effects to the schedule IV substances alprazolam and phenobarbital. In clinical trials, lacosamide produced subjective responses similar to alprazolam but these effects did not last as long as alprazolam. After careful consideration of positive indicators from preclinical and clinical studies, DEA finds lacosamide has abuse potential supporting placement in schedule V under the CSA. The DHHS recommended control in schedule V of the CSA and the DEA concurs.

The commenter also submitted a request for a hearing. DEA regulations provide that ''[a]ny interested person'' may request a hearing on a proposed scheduling action. 21 CFR 1308.44(a). DEA regulations define ''interested person'' as ''any person adversely affected or aggrieved by any rule or proposed rule issuable pursuant to [21 U.S.C. 811].'' 21 CFR 1300.01(b)(19). The regulations further require that any person requesting a hearing must state ''with particularity'' his interest in the proceeding. 21 CFR 1316.47(a). The commenter failed to provide sufficient information to demonstrate that he meets the definition of ''interested person'' as set forth in the regulations, therefore DEA is denying his hearing request.

DEA also received many comments after the comment period closed. These late comments were not considered by DEA.

Scheduling of Lacosamide

Based on the scientific and medical evaluation and the recommendation of the Assistant Secretary for Health, received in accordance with section 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by the DEA, the Deputy Administrator of the DEA, pursuant to sections 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Lacosamide has a low potential for abuse relative to the drugs or other substances in schedule IV;

(2) Lacosamide has a currently accepted medical use in treatment in the United States; and

(3) Abuse of lacosamide may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in schedule IV.

Based on these findings, the Deputy Administrator of the DEA concludes that lacosamide and any material, compound, mixture, or preparation which contains any quantity of lacosamide, warrant control in schedule V of the CSA.

Requirements for Handling Lacosamide

Registration. Any person who manufactures, distributes, dispenses,

imports, exports, engages in research or conducts instructional activities with lacosamide, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with lacosamide, must be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations (CFR). Any person who is currently engaged in any of the above activities and is not registered with DEA must submit an application for registration on or before June 22, 2009 and may continue their activities until the DEA has approved or denied the application.

Security. Lacosamide is subject to schedule III–V security requirements and must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(b), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76, and 1301.77 of Title 21 of the CFR on and after June 22, 2009.

Labeling and Packaging. All labels and labeling for commercial containers of lacosamide which are distributed on or after June 22, 2009 must comply with requirements of §§ 1302.03–1302.07 of Title 21 of the Code of Federal Regulations.

Inventory. Every registrant required to keep records and who possesses any quantity of lacosamide must keep an inventory of all stocks of lacosamide on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the CFR on or after June 22, 2009. Every registrant who desires registration in schedule V for lacosamide must conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants must keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

Prescriptions. All prescriptions for lacosamide pharmaceutical products must be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.23–1306.27 on or after June 22, 2009.

Importation and Exportation. All importation and exportation of lacosamide must be in compliance with part 1312 of Title 21 of the CFR on or after June 22, 2009.

Criminal Liability. Any activity with lacosamide not authorized by, or in violation of, the CSA or the Controlled Substances Import and Export Act occurring on or after June 22, 2009 shall be unlawful.

Regulatory Certifications

Executive Order 12866

In accordance with the provisions of the CSA (21 U.S.C. 811(a)), this action is a formal rulemaking ''on the record after opportunity for a hearing.'' Such proceedings are conducted pursuant to the provisions of 5 U.S.C. 556 and 557 and, as such, are exempt from review by the Office of Management and Budget pursuant to Executive Order 12866, § 3(d)(1).

Regulatory Flexibility Act

The Deputy Administrator, in accordance with the Regulatory Flexibility Act (5 U.S.C. 601–612), has reviewed this final rule and by approving it certifies that it will not have a significant economic impact on a substantial number of small entities. Lacosamide pharmaceutical products will be prescription drugs used for the treatment of partial-onset seizures. Handlers of lacosamide often handle other controlled substances used in the treatment of central nervous system disorders which are already subject to the regulatory requirements of the CSA.

Executive Order 12988

This regulation meets the applicable standards set forth in §§ 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform.

Executive Order 13132

This rulemaking does not preempt or modify any provision of State law; nor does it impose enforcement responsibilities on any state; nor does it diminish the power of any state to enforce its own laws. Accordingly, this rulemaking does not have federalism implications warranting the application of Executive Order 13132.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by state, local and tribal governments, in the aggregate, or by the private sector, of $120,000,000 or more (adjusted for inflation) in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under provisions of the Unfunded Mandates Reform Act of 1995.

Congressional Review Act

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act). This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices: or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign based companies in domestic and export markets.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Narcotics, Prescription drugs.

■ Under the authority vested in the Attorney General by section 201(a) of the CSA (21 U.S.C. 811(a)), and delegated to the Administrator of DEA by Department of Justice regulations (28 CFR 0.100), and redelegated to the Deputy Administrator pursuant to Title 28, Part 0, Appendix to Subpart R, Section 12, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for 21 CFR part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b) unless otherwise noted.

■ 2. Section 1308.15 is amended by revising paragraph (e)(1) and adding a new paragraph (e)(2) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(e) * * *

(1) Lacosamide [(*R*)-2-acetoamido-*N*-benzyl-3-methoxy-propionamide]—2746

(2) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid]—2782

Dated: May 12, 2009.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E9–11927 Filed 5–20–09; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–319F]

Schedules of Controlled Substances: Placement of Tapentadol Into Schedule II

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final rule.

SUMMARY: With the issuance of this final rule, the Deputy Administrator of the Drug Enforcement Administration (DEA) places the substance tapentadol, 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, into schedule II of the