

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]

BILLING CODE 4410–09–P

## 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

Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of schedule II will be applicable to the manufacture, distribution, dispensing, importation, and exportation of tapentadol and products containing tapentadol.

**DATES:** *Effective Date:* 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 Morrisette Drive, Springfield, Virginia 22152, *Telephone:* (202) 307-7183.

**SUPPLEMENTARY INFORMATION:**

**Background**

On November 20, 2008, the Food and Drug Administration (FDA) approved tapentadol for marketing in the United States as a prescription drug product for the treatment of moderate-to-severe acute pain. Tapentadol is a new molecular entity with centrally-acting analgesic properties.

Tapentadol has dual modes of action, namely mu ( $\mu$ ) opioid receptor agonistic action and inhibition of reuptake of norepinephrine at the norepinephrine transporter. The chemical name of its monohydrochloride salt form is 3-[(1R,2R)-3-(dimethylamino)-1-ethyl-2-methylpropyl]phenol hydrochloride. Tapentadol shares substantial pharmacological effects and abuse potential with other schedule II opioid analgesics, e.g., morphine, oxycodone, and hydromorphone.

Since tapentadol is a new molecular entity, there has been no evidence of diversion, abuse, or law enforcement encounters involving the drug.

On November 13, 2008, the Assistant Secretary for Health, Department of Health and Human Services (DHHS), sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that tapentadol be placed into schedule II of the CSA. Enclosed with the November 13, 2008, letter was a document prepared by the Food and Drug Administration (FDA) entitled, "Basis for the Recommendation for Control of Tapentadol in Schedule II of the Controlled Substances Act." The document contained a review of the factors which the CSA requires the Secretary to consider (21 U.S.C. 811(b)).

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation from DHHS, the Deputy Administrator of the DEA published a Notice of Proposed Rulemaking entitled "Schedules of Controlled Substances: Placement of

Tapentadol into Schedule II" on February 17, 2009 (74 FR 7386), which proposed placement of tapentadol into schedule II of the CSA. The proposed rule provided an opportunity for all interested persons to submit their written comments on or before March 19, 2009.

**Comments Received**

The DEA received three comments in response to the Notice of Proposed Rulemaking. One comment was from a consulting firm, one comment was from a concerned citizen, and the last comment was from a company which does research and development on pharmaceutical drugs.

The first commenter recommended that the DEA expedite the issuance and effective date of the Final Rule placing tapentadol in schedule II. The commenter stated that tapentadol will provide a safe and effective substitute for other schedule II analgesics and that the conditions of public health necessitate and justify this request. In response, DEA believes that providing 30 days for this rule to become effective is both expeditious and sufficient to allow handlers to apply for registration with DEA and to comply with the regulatory requirements for handling schedule II controlled substances.

A second commenter stated that since tapentadol induces effects similar to oxycodone and morphine, both schedule II substances, then it should be placed in schedule II of the Controlled Substances Act based on tapentadol's abuse potential. Thus, the commenter agreed with DHHS' recommendation and the action proposed by DEA. No response from DEA is necessary to this comment because it is consistent with the DEA's final action.

The third commenter had four questions/comments regarding the implementation of this Final Rule. Each question/comment is addressed below.

The commenter requested that DEA registrants be allowed enough time to make the changes needed to carry out handling tapentadol as a schedule II substance, as dictated in 21 CFR 1301.51, 1301.71, and 1304.04. In response to this comment, the effective date of the Final Rule placing tapentadol in schedule II of the Controlled Substances Act will be thirty (30) days from the date of publication of the Final Rule, thus allowing ample time for those that wish to handle tapentadol to meet DEA regulatory requirements for handling schedule II substances. It has been DEA's experience that this is sufficient time to meet the regulatory requirements provided below.

The commenter asked if quantities of tapentadol held by a DEA registrant would have to be reported once the scheduling of tapentadol as a schedule II substance was finalized. In response, the reporting and recordkeeping requirements for handling schedule II substances can be found in 21 CFR part 1304. Specifically, 21 CFR 1304.11(b) states that "Every person required to keep records shall take an inventory of all stocks of controlled substances on hand on the date he/she first engages in the manufacture, distribution, or dispensing of controlled substances \* \* \*" In order for a manufacturer to handle a schedule II substance, a manufacturing or procurement quota has to be requested in accordance with the requirements of 21 U.S.C. 826(c) and 21 CFR part 1303. The manufacturer's inventory of the substance is used, in part, to determine the manufacturer's quota.

The commenter asked about the process for adding the CSA drug code for tapentadol to their registration. In response, the regulatory process required to obtain a DEA registration is outlined generally in 21 CFR 1301.11 through 1301.19, and the process required to modify an existing DEA registration is outlined in 21 CFR 1301.51. Information relating to registration may be found on the Internet, <http://www.DEAdiversion.usdoj.gov>, or by contacting DEA's Registration Call Center, toll free at 1-800-882-9539.

Finally, the commenter inquired about the process for establishing an NDC number for tapentadol with the Automation of Reports and Consolidated Orders System (ARCOS). National Drug Code (NDC) numbers are assigned by the Food and Drug Administration (FDA) in conjunction with registration and drug listing requirements of the Federal Food, Drug, and Cosmetic Act. Accordingly, a person manufacturing a product containing tapentadol must obtain an NDC number from FDA in accordance with 21 CFR 207.35. Once the drug code for tapentadol is added to an existing manufacturer's registration or a new registration is issued to an applicant, then that DEA-registered manufacturer must provide the DEA's ARCOS Unit with its established NDC number for their product containing tapentadol. Once that information is obtained, it can be used to report ARCOS reportable transactions pursuant to 21 CFR 1304.33.

**Scheduling of Tapentadol**

Based on the recommendation of the Assistant Secretary for Health, received

in accordance with § 201(b) of the Act (21 U.S.C. 811(b)), and the independent review of the available data by DEA, and after a review of the comments received in response to the Notice of Proposed Rulemaking, the Deputy Administrator of DEA, pursuant to §§ 201(a) and 201(b) of the Act (21 U.S.C. 811(a) and 811(b)), finds that:

(1) Tapentadol has a high potential for abuse;

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

(3) Abuse of tapentadol may lead to severe psychological or physical dependence.

Based on these findings, the Deputy Administrator of DEA concludes that 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, warrants control in schedule II of the CSA (21 U.S.C. 812(b)(2)).

#### Requirements for Handling Tapentadol

**Registration.** Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with tapentadol, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with tapentadol, must be registered to conduct such activities in accordance with part 1301 of Title 21 of the Code of Federal Regulations. 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 DEA has approved or denied that application.

**Security.** Tapentadol is subject to schedule II security requirements and must be manufactured, distributed, and stored in accordance with §§ 1301.71, 1301.72(a), (c), and (d), 1301.73, 1301.74, 1301.75(b) and (c), 1301.76 and 1301.77 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Labeling and Packaging.** All labels and labeling for commercial containers of tapentadol must comply with requirements of §§ 1302.03 through 1302.07 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Quotas.** Quotas for tapentadol must be established pursuant to part 1303 of Title 21 of the Code of Federal Regulations.

**Inventory.** Every registrant required to keep records and who possesses any quantity of tapentadol must keep an

inventory of all stocks of tapentadol on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on or after June 22, 2009. Every registrant who desires registration in schedule II for tapentadol 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.

**Reports.** All registrants required to submit reports to the Automation of Reports and Consolidated Order System (ARCOS) in accordance with § 1304.33 of Title 21 of the Code of Federal Regulations must do so for tapentadol.

**Orders for Tapentadol.** All registrants involved in the distribution of tapentadol must comply with the order form requirements of part 1305 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

**Prescriptions.** All prescriptions for tapentadol or prescriptions for products containing tapentadol must be issued pursuant to §§ 1306.03 through 1306.06 and 1306.11 through 1306.15 of Title 21 of the Code of Federal Regulations on and after June 22, 2009.

**Importation and Exportation.** All importation and exportation of tapentadol must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on or after June 22, 2009.

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

#### 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, section 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. Tapentadol products will be prescription drugs used for the

treatment of moderate-to-severe acute pain. Handlers of tapentadol also handle other controlled substances used to treat pain which are already subject to the regulatory requirements of the CSA.

##### *Executive Order 12988*

This regulation meets the applicable standards set forth in Sections 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 section 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 part 1308 continues to read as follows:

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

■ 2. Section 1308.12 is amended in the table by adding a new paragraph (c)(28) to read as follows:

**§ 1308.12 Schedule II.**

\* \* \* \* \*

(c) \* \* \*

(28) Tapentadol ..... 9780

\* \* \* \* \*

Dated: May 15, 2009.

**Michele M. Leonhart,***Deputy Administrator.*

[FR Doc. E9-11933 Filed 5-20-09; 8:45 am]

BILLING CODE 4410-09-P

**DEPARTMENT OF HOMELAND SECURITY****Coast Guard****33 CFR Part 165**

[Docket No. USCG-2009-0089]

RIN 1625-AA00

**Safety Zone; Red Bull Air Race, Detroit River, Detroit, MI****AGENCY:** Coast Guard, DHS.**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the Detroit River, Detroit, Michigan. This zone will restrict vessels from portions of the Detroit River during the Red Bull Air Race. This temporary safety zone is necessary to protect spectators and vessels from the hazards associated with air races.

**DATES:** This rule is effective from 9 a.m. on June 11, 2009 through 6:30 p.m. on June 14, 2009.

**ADDRESSES:** Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0089 and are available online by going to <http://www.regulations.gov>, selecting the Advanced Docket Search option on the right side of the screen, inserting USCG-2009-0089 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground

Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this rule, call or e-mail CDR Joseph Snowden, Prevention Department, Sector Detroit, Coast Guard; telephone (313) 568-9580, e-mail [Joseph.H.Snowden@uscg.mil](mailto:Joseph.H.Snowden@uscg.mil). If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:****Regulatory Information**

On April 16, 2009, we published a notice of proposed rulemaking (NPRM) entitled Safety Zone; Red Bull Air Race, Detroit River, Detroit, MI in the **Federal Register** (74 FR 17627). We received one comment on the proposed rule. No public meeting was requested, and none was held.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Delaying this rule would be contrary to the public interest of ensuring, to the extent practicable, the safety and security of the spectators and participants during this event and immediate action is necessary to prevent possible injury, loss of life, or property.

**Background and Purpose**

This temporary safety zone is necessary to ensure, to the extent practicable, the safety of vessels and spectators from hazards associated with an air race. The Captain of the Port Detroit has determined air races in close proximity to watercraft and infrastructure pose significant risk to public safety and property. The likely combination of large numbers of recreation vessels, possible alcohol use, airplanes traveling at high speeds and performing aerial acrobatics, and large numbers of spectators in close proximity to the water could easily result in serious injuries or fatalities. Establishing a safety zone around the location of the race course will help ensure the safety of persons and property at these events and help minimize the associated risks.

**Discussion of Comments and Changes**

We received one letter, containing several comments on this rulemaking. First, the commenter stated that closure of the Detroit River for these air races violates the Boundary Waters Treaty of 1909. The Coast Guard disagrees that the Coast Guard's action or the action by

Canada violates this treaty. The Boundary Waters Treaty does guarantee that "navigation of all navigable boundary waters" shall be "free and open" to "inhabitants \* \* \* ships, vessels, and boats" of both the United States and Canada, "subject, however, to any laws and regulations of either country." Both the United States and Canada have determined, pursuant to each country's laws and regulations, that brief closures of the Detroit River are reasonably necessary to protect spectators and vessels from hazards associated with these air races. Moreover, under fundamental principles of international law, only the States that are a party to an international agreement are generally entitled to allege a breach of the terms of the agreement by the other. For this event, Canada has also agreed that a closure of a small portion of the river for a short period of time is a reasonable and necessary measure.

Second, the commenter stated that the proposed rule constituted a "public taking" in contravention of the Fifth Amendment to the United States Constitution; in that vessel owners will experience delays that will result in lost profits. This commenter did not put forward any specific company or vessel that would be so affected. The Coast Guard disagrees with this comment. In general, a "taking" occurs when a governmental entity uses its powers to permanently deprive a person or entity of property. The Captain of the Port has considered the needs of port stakeholders and the maritime community and has determined that this safety zone is necessary to protect the public and maintain safety of navigation. Further, the rule is only temporary in nature, not permanent, and in the event that this temporary safety zone affects shipping, commercial vessels may request permission from the Captain of the Port Detroit to transit through the safety zone. Moreover, the safety zone will only be enforced for a short period of time on the enforcement dates. Lastly, the Coast Guard believes vessel owners have had sufficient advance notice of this safety zone, such that they should be able to work vessel schedules around the enforcement periods of the proposed safety zone to minimize or avoid lost profits.

Third, the commenter stated that the race sponsor must be required to agree in advance to reasonably compensate vessel owners for losses incurred by delays and post a bond sufficient to cover anticipated vessel losses. Otherwise, this commenter stated, there is no incentive for race organizers to work collaboratively with vessel