

hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on and after July 28, 2005. Every registrant who desires registration in Schedule V for pregabalin is required to 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 and after July 28, 2005.

Prescriptions. All prescriptions for pregabalin or prescriptions for products containing pregabalin must be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21, 1306.23–1306.27.

Importation and Exportation. All importation and exportation of pregabalin must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on and after July 28, 2005.

Criminal Liability. Any activity with pregabalin not authorized by, or in violation of, the Controlled Substances Act or the Controlled Substances Import and Export Act occurring on and after July 28, 2005, shall be unlawful.

Regulatory Certifications

Administrative Procedure Act

The Administrative Procedure Act permits an agency to make a rule effective upon the date of publication when the agency finds good cause exists and publishes its findings with the rule (5 U.S.C. 553(d)(3)). As noted previously, on December 31, 2004, the FDA approved pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] for marketing under the trade name Lyrica. On April 4, 2005, the Acting Assistant Secretary for Health of the DHHS sent the Administrator of the DEA a scientific and medical evaluation and a scheduling recommendation that pregabalin, and its salts, be placed in Schedule V of the CSA. Since this is a new drug not previously available in the United States and the first drug product specifically approved for the treatment of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN), in order to prevent harm to the public health and safety by delaying the availability of this new drug, the DEA finds good cause to make this Final Rule effective immediately upon publication.

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. 605(b)), 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. Pregabalin products will be prescription drugs used for the treatment of neuropathic pain. Handlers of pregabalin often handle other controlled substances used to treat pain which are already subject to the regulatory requirements of the CSA.

Pregabalin is a new drug in the United States; recent approval of Lyrica™ by the FDA will allow it to be marketed once it is placed into Schedule V of the CSA. This final rule will allow medical access to a new pharmaceutical product.

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 \$115,000,000 or more 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.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by § 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. 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 28 CFR 0.104, the Deputy Administrator hereby amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES [AMENDED]

■ 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 adding a new paragraph (e) to read as follows:

§ 1308.15 Schedule V.

* * * * *

(e) *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) Pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] 2782

(2) [Reserved]

Dated: July 22, 2005.

Michele M. Leonhart,
Deputy Administrator.

[FR Doc. 05–15036 Filed 7–27–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[TD 9186]

RIN 1545–BD42

Qualified Amended Returns; Correction

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Correction to a correction to temporary regulations.

SUMMARY: This document corrects a correction to temporary regulations (TD 9186) which was published in the **Federal Register** on June 23, 2005 (70 FR 36345). The temporary regulations modify the rules relating to qualified amended returns by providing additional circumstances that end the period within which a taxpayer may file an amended return that constitutes a qualified amended return.

DATES: This correction is effective on March 2, 2005.

FOR FURTHER INFORMATION CONTACT: Nancy Galib, (202) 622-4940 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

The temporary regulations (TD 9186) that is the subject of this correction is under section 6664 of the Internal Revenue Code.

Need for Correction

As published, the correction to the temporary regulations (TD 9186) contains an error that may prove to be misleading and is in need of clarification.

Correction of Publication

Accordingly, the publication of the correction to the temporary regulations (TD 9186) that is the subject of FR Doc. 05-12386, is corrected as follows:

On page 36345, column 2, in the preamble, under the paragraph heading "Background", line 3, the language "are under section 6227 of the Internal" is corrected to read "are under section 6664 of the Internal".

Cynthia E. Grigsby,

Acting Chief, Publications and Regulations Branch, Legal Processing Division, Associate Chief Counsel, (Procedures and Administration).

[FR Doc. 05-14902 Filed 7-27-05; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD13-05-030]

RIN 1625-AA11

Safety Zone: Camp Rilea Offshore Small Arms Firing Range; Warrenton, OR

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone offshore of Camp Rilea, Warrenton, Oregon. Small arms training and fire will be conducted within this zone, and a safety zone is needed to ensure the safety of persons and vessels operating in this area during the specified periods. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative.

DATES: This rule is effective from 6 a.m. July 25, 2005 through 9 p.m. July 29, 2005.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket CGD13-05-030 and are available for inspection or copying at Coast Guard Sector Portland, 6767 North Basin Avenue, Portland, OR 97217-3992 between 7 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Shadrack Scheirman, Chief Port Operations, USCG Sector, Portland, OR 97217, telephone number (503) 240-9310.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for not publishing an NPRM and for making this rule effective less than 30 days after publication in the **Federal Register**.

In order to maintain an increased maritime security posture, the Coast Guard has increased training requirements for the carriage of weapons during homeland security operations. The crews required to carry out homeland security operations must be trained to perform their operational obligations. Crews from multiple units along the Oregon and Washington coasts are participating in this exercise. Unit operational schedules converged to make July 25-29 the only date to accommodate all parties.

Publishing an NPRM and delaying the effective date of this rule would be contrary to the public interest since immediate action is necessary to minimize potential danger to the public from small arms fire during the live fire training. Such training is necessary in order to ensure Coast Guard crews are qualified to carry Crew Served Weapons required to fulfill their Military and Homeland Security responsibilities.

Background and Purpose

Changes in Coast Guard policy and procedures require small boat crews to train on and fire crew served weapons from a vessel. In order to ensure the safety of persons and vessels operating in vicinity of this training from July 25, 2005 through July 29, 2005 a safety zone will be in effect during all small arms firing evolutions.

Discussion of Rule

This safety zone will be in effect to ensure the safety of persons and vessels in the vicinity of the live fire training. Entry into this safety zone is prohibited unless authorized by the Captain of the Port or his/her designated representative. A Coast Guard vessel will be on scene to ensure that the public is aware that the firing exercises are in progress and that the firing area is clear of traffic before firing commences. All persons and vessels shall comply with the instructions of the Captain of the Port or his/her designated on-scene U.S. Coast Guard representative. On-scene Coast Guard patrol personnel include commissioned, warrant, and petty officers of the Coast Guard on board Coast Guard, Coast Guard Auxiliary, and local, state, and federal law enforcement vessels.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the regulatory policies and procedures of the Department of Homeland Security (DHS). This rule only affects a small area for a limited duration. The proposed regulations have been tailored in scope to impose the least impact on maritime interests, yet provide the level of safety necessary for such an event.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have