or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any 1 year.'' FDA has determined that this proposed rule does not constitute a significant regulatory action under the Unfunded Mandates Reform Act.

VIII. Environmental Impact

FDA has determined under 21 CFR 25.32(p) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

IX. Paperwork Reduction Act

FDA concludes that this proposed rule contains no collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

X. Federalism

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States or on the relationship between the National Government and the States, or on the distribution of power and responsibility among the various levels of government. Accordingly, FDA has concluded that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XI. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments in response to FDA's proposed rule. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

XII. Proposed Effective Date

FDA proposes that any final regulation that may issue based on this proposal become effective 30 days after its date of publication in the **Federal Register**.

XIII. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. McNeil Nutritionals, ''Petition to Amend 21 CFR 101.80 to Authorize a Noncariogenicity Dental Health Claim for Sucralose,'' CP–1, Docket No. 2004P–0294, April 2, 2004.

2. U.S. Department of Health and Human Services, ''Oral Health,'' chapter 21, *Healthy People 2010*, volume II, part B, 2d ed., Washington, DC: U.S. Government Printing Office (*www.health.gov/healthypeople/Document/HTML/Volume2/21Oral.htm*, visited 03/17/2005), November 2000.

3. G.A. Miller, ''Sucralose,'' *Alternative Sweeteners, 2d ed.* L.O. Nabors and R.C. Gelardi, eds. Marcel Dekker, Atlanta, pp. 173–175, 1991.

4. P. Lingström, T. Imfeld, and D. Birkhed, ''Comparison of Three Different Methods for Measurement of Plaque-pH in Humans After Consumption of Soft Bread and Potato Chips,'' *Journal of Dental Research*, 72:865–870, 1993.

5. D.S. Harper, R. Gray, J.W. Lenke, et al., ''Measurement of Human Plaque Acidity: Comparison of Interdental Touch and Indwelling Electrodes,'' *Caries Research*, 19:536–546, 1985.

6. M.E. Jensen and C.F. Schachtele, ''Plaque pH Measurements by Different Methods on the Buccal and Approximal Surfaces of Human Teeth After Sucrose Rinse,'' *Journal of Dental Research*, 62:1058–1061, 1983.

7. L.M. Steinberg, F. Odusola, J. Yip, et al., ''Effect of Aqueous Solutions of Sucralose on Plaque pH,'' *American Journal of Dentistry*, 8:209–211, 1995.

8. L.M. Steinberg, F. Odusola, J. Yip, et al., ''Effect of Sucralose in Coffee on Plaque pH in Human Subjects,'' *Caries Research*, 30:138–142, 1996.

9. C. Meyerowitz, E.P. Syrrakov, and R.F. Raubertas, ''Effect of Sucralose—Alone or Bulked With Maltodextrin and/or Dextrose—on Plaque pH in Humans,'' *Caries Research*, 30:439–444, 1996.

10. D.A. Young and W.H. Bowen, ''The Influence of Sucralose on Bacterial Metabolism,'' *Journal of Dental Research*, 69:1480–1484, 1990.

11. D.B. Drucker and J. Verron, ''Comparative Effects of the Substance Sweeteners Glucose, Sorbitol, Sucrose, Xylitol, and Trichlorosucrose on Lowering of pH by Two Oral *Streptococcus Mutans* Strains In Vitro,'' *Archives of Oral Biology*, 24:965–970, 1980.

12. W.H. Bowen, D.A. Young, and S.K. Pearson, ''The Effects of Sucralose on Coronal and Root-Surface Caries,'' *Journal of Dental Research*, 69:1485–1487, 1990.

13. W.H. Bowen, S.K. Pearson, and J.L. Falany, ''Influence of Sweetening Agents in Solution on Dental Caries in Desalivated Rats,'' *Archives of Oral Biology*, 35:839–844, 1990.

14. Department of Health and Human Services, Results of National Oral Health Survey Results Released (press release) (*http://www.hhs.gov/news/press/1996pres/960311.html*, visited on 03/17/2005), March 11, 1996.

15. U.S. Department of Health and Human Services, *Oral Health in America: A Report of the Surgeon General*—Executive Summary, Rockville, MD, U.S. Department of Health and Human Services, National Institute of Dental and Craniofacial Research, National Institutes of Health, (*http://www2.nidcr.nih.gov/sgr/execsumm.htm*, visited on 03/17/2005), 2000.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 101 is proposed to be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: 15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 342, 343, 348, 371; 42 U.S.C. 243, 264, 271.

2. Section 101.80 is amended by adding (c)(2)(ii)(C) and (e)(1)(v) to read as follows:

§ 101.80 Health claims: dietary noncariogenic carbohydrate sweeteners and dental caries.

* * * * *

(c) * * *

(2) * * *

(ii) * * *

(C) Sucralose.

* * * * *

(e) * * *

(1) * * *

(v) Frequent eating of foods high in sugars and starches as between-meal snacks can promote tooth decay. Sucralose, the sweetening ingredient used to sweeten this food, unlike sugars, does not promote tooth decay.

Dated: May 4, 2005..

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–9608 Filed 5–12–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–267P]

Schedules of Controlled Substances: Placement of Pregabalin into Schedule V

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule is issued by the Deputy Administrator of the Drug Enforcement Administration (DEA) to place the substance pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid], including its salts, and all products containing pregabalin into Schedule V of the Controlled Substances Act (CSA). This proposed action is based on a recommendation from the Acting Assistant Secretary for Health of the Department of Health and Human Services (DHHS) and on an evaluation of the relevant data by DEA. If finalized, this action will impose the regulatory controls and criminal sanctions applicable to Schedule V non-narcotics on those who handle pregabalin and products containing pregabalin.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before June 13, 2005.

ADDRESSES: To ensure proper handling of comments, please reference ''Docket No. DEA–267P'' on all written and electronic correspondence. Written comments being sent via regular mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA Federal Register Representative/ODL. Written comments sent via express mail should be sent to the Deputy Administrator, Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODL, 2401 Jefferson-Davis Highway, Alexandria, VA 22301. Comments may be directly sent to DEA electronically by sending an electronic message to *dea.diversion.policy@usdoj.gov.* Comments may also be sent electronically through *http://www.regulations.gov* using the electronic comment form provided on that site. An electronic copy of this document is also available at the *http://www.regulations.gov* Web site. DEA will accept electronic comments containing MS Word, WordPerfect, Adobe PDF, or Excel file formats only. DEA will not accept any file format other than those specifically listed here.

FOR FURTHER INFORMATION CONTACT: Christine Sannerud, Ph.D., Chief, Drug and Chemical Evaluation Section, Drug Enforcement Administration, Washington, DC 20537, (202) 307–7183.

SUPPLEMENTARY INFORMATION:

Note Regarding This Scheduling Action

In accordance with the provisions of the Controlled Substances Act (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 the Administrative Procedure Act (5 U.S.C. 556 and 557). Interested persons are invited to submit their comments, objections or requests for a hearing with regard to this proposal. Requests for a hearing should be made in accordance with 21 CFR 1308.44 and should state, with particularity, the issues concerning which the person desires to be heard. All correspondence regarding this matter should be submitted to the Drug Enforcement Administration using the address information provided above.

Background

On December 31, 2004, the Food and Drug Administration (FDA) approved pregabalin [(S)-3-(aminomethyl)-5-methylhexanoic acid] for marketing under the trade name Lyrica™. Lyrica™ will be marketed in the United States as a prescription drug product for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN). Pregabalin has recently been placed on the market in some European countries for the treatment of epilepsy and neuropathic pain.

Unlike morphine-type analgesics, pregabalin does not produce analgesia through binding at opioid receptors. While pregabalin is an analog of gamma-aminobutyric acid (GABA), a major inhibitory neurotransmitter in the brain, it does not bind at GABA or benzodiazepine receptors nor alter GABA concentrations in the brain. Pregabalin does bind with high affinity to the alpha 2-delta receptor site (a subunit of voltage-gated calcium channels) in the central nervous system. The binding of pregabalin at this site is thought to be responsible for its therapeutic effect on neuropathic pain.

Pregabalin has been shown to produce effects that are similar to other controlled substances. In a study with recreational users of sedative/hypnotic drugs, a 450 mg dose of pregabalin resulted in subjective ratings of ''good drug effect,'' ''high,'' and ''liking'' similar to 30 mg of diazepam. In clinical studies, pregabalin showed an adverse event profile similar to other central nervous system depressants. Some of these effects included dizziness, somnolence, ataxia, and confusion. Following abrupt or rapid discontinuation of pregabalin, some patients reported symptoms suggestive of physical dependence. The FDA determined that the dependence profile of pregabalin, as measured by a patient physical withdrawal checklist, was quantitatively less than benzodiazepines in schedule IV of the CSA.

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 letter recommending that pregabalin be placed into Schedule V of the CSA. Enclosed with the April 4, 2005, letter was a document prepared by the FDA entitled, ''Basis for the Recommendation for Control of Pregabalin 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)).

The factors considered by the Acting Assistant Secretary of Health and DEA with respect to pregabalin were:

(1) Its actual or relative potential for abuse;

(2) Scientific evidence of its pharmacological effects;

(3) The state of current scientific knowledge regarding the drug;

(4) Its history and current pattern of abuse;

(5) The scope, duration, and significance 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 under this subchapter. (21 U.S.C. 811(c))

Based on the recommendation of the Acting 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) Based on information now available, pregabalin has a low potential for abuse relative to the drugs or other substances in Schedule IV;

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

(3) Abuse of pregabalin may lead to limited physical dependence or psychological dependence relative to the drugs or other substances in Schedule IV. (21 U.S.C. 812(b)(5))

Based on these findings, the Deputy Administrator of the DEA concludes that pregabalin, including its salts, and all products containing pregabalin, warrant control in Schedule V of the CSA.

Interested persons are invited to submit their comments, objections or requests for a hearing with regard to this proposal. Requests for a hearing should state, with particularity, the issues concerning which the person desires to

be heard. All correspondence regarding this matter should be submitted to the Drug Enforcement Administration using the address information provided above. In the event that comments, objections, or requests for a hearing raise one or more issues which the Deputy Administrator finds warrant a hearing, the Deputy Administrator shall order a public hearing by notice in the **Federal Register**, summarizing the issues to be heard and setting the time for the hearing.

Requirements for Handling Pregabalin

If this rule is finalized as proposed, pregabalin and all products containing pregabalin would be subject to the Controlled Substances Act and the Controlled Substances Import and Export Act regulatory controls and administrative, civil and criminal sanctions applicable to the manufacture, distribution, dispensing, importing and exporting of a Schedule V controlled substance, including the following:

Registration. Any person who manufactures, distributes, dispenses, imports, exports, engages in research or conducts instructional activities with pregabalin, or who desires to manufacture, distribute, dispense, import, export, engage in instructional activities or conduct research with pregabalin, would need to be registered to conduct such activities in accordance with Part 1301 of Title 21 of the Code of Federal Regulations.

Security. Pregabalin would be 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 Code of Federal Regulations.

Labeling and Packaging. All labels and labeling for commercial containers of pregabalin which are distributed on or after finalization of this rule would need to 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 pregabalin would be required to keep an inventory of all stocks of pregabalin on hand pursuant to §§ 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations. Every registrant who desires registration in Schedule V for pregabalin would be required to conduct an inventory of all stocks of the substance on hand at the time of registration.

Records. All registrants would be required to keep records pursuant to §§ 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations.

Prescriptions. All prescriptions for pregabalin or prescriptions for products containing pregabalin would be required to 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 would need to be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

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 or after finalization of this proposed rule would 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, 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 proposed 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.

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 proposes that 21 CFR part 1308 be amended 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 proposed to be 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: May 6, 2005.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. 05–9634 Filed 5–12–05; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD01–05–041]

RIN 1625–AA00

Safety Zone; Beverly Homecoming Fireworks, Beverly, MA

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to establish a temporary safety zone for the Beverly Homecoming Fireworks in Beverly, Massachusetts. This safety zone is necessary to protect the life and property of the maritime public from potential hazards associated with a fireworks display. The safety zone would temporarily prohibit entry into or movement within this portion of Beverly Harbor during the closure period.

DATES: Comments and related material must reach the Coast Guard on or before June 13, 2005.

ADDRESSES: You may mail comments and related material to Coast Guard Sector Boston, 427 Commercial Street, Boston, MA 02109. Sector Boston maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket are part of docket CGD01–05–041 and are available for inspection or copying at Sector Boston, 427 Commercial Street, Boston, MA, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Chief Petty Officer Paul English, Sector Boston, Waterways Safety and Response Division, at (617) 223–3010.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking (CGD01–05–041), indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know that your submission reached us, please enclose a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to Sector Boston at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

This rule proposes to establish a safety zone in Beverly Harbor within a 400-yard radius of the fireworks barge located at approximate position 42°32′35″ N, 070°52′00″ W. The safety zone would be in effect from 8 p.m. until 10:30 p.m. EDT on August 7, 2005.

The safety zone would temporarily restrict movement within the effected portion of Beverly Harbor and is needed to protect the maritime public from the dangers posed by a fireworks display. Marine traffic may transit safely outside of the safety zone during the effective period. The Captain of the Port does not anticipate any negative impact on vessel traffic due to this event. Public notifications will be made prior to the effective period of this proposed rule via safety marine information broadcasts and Local Notice to Mariners.

Discussion of Proposed Rule

The Coast Guard is establishing a temporary safety zone in Beverly Harbor, Beverly, Massachusetts. The safety zone would be in effect from 8 p.m. until 10:30 p.m. EDT on August 7, 2005. Marine traffic may transit safely outside of the safety zone in the majority of Beverly Harbor during the event. This safety zone will control vessel traffic during the fireworks display to protect the safety of the maritime public.

Due to the limited timeframe of the fireworks display and because the zone leaves the majority of Beverly Harbor open for navigation, the Captain of the Port anticipates minimal negative impact on vessel traffic due to this event. Public notifications will be made prior to the effective period via Local Notice to Mariners and marine information broadcasts.

Regulatory Evaluation

This proposed 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).

The Coast Guard expects the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary.

Although this rule will prevent traffic from transiting a portion of Beverly Harbor during the effective period, the effects of this rule will not be significant for several reasons: vessels will only be excluded from the proscribed area for two and one half hours, vessels will be able to operate in the majority of Beverly Harbor during this time, and advance notifications will be made to the local maritime community by marine information broadcasts and Local Notice to Mariners.

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 proposed rule would not have a significant economic impact on a substantial number of small entities.

This proposed rule would affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in effected portion of Beverly Harbor from 8 p.m. until 10:30 p.m. EDT on August 7, 2005.

This safety zone would not have a significant economic impact on a substantial number of small entities for the following reasons: this proposed rule would be in effect for only two and one half hours, vessel traffic can safely pass around the safety zone during the effected period, and advance notifications will be made to the local maritime community by marine