

Approximately 251 companies (primarily importers) are currently serviced by the airport.

CBP facilities are already in place at the Tri-Cities Regional User Fee Airport. CBP believes that the establishment of this port will provide significant benefits to the local community, further enhancing the economic growth that is already being experienced in this area, by providing enhanced business competitiveness for existing enterprises and enabling the retention and expansion of the number of jobs in the area.

The Tri-Cities Regional Airport is committed to continue making the optimal use of electronic data transfer capability to permit integration with the CBP Automated Commercial System for processing entries. This commitment is shown in the current financial support, furnished by the Tri-Cities Airport Commission, of an interstate dedicated data line and computer upgrades. Since October 1, 2003, two companies, each with the automated capacity to interface with CBP, have occupied established offices in the Tri-Cities Airport.

Description of Proposed Port-of-Entry Limits

The geographical limits of the proposed Tri-Cities, TN/VA, port of entry would be as follows:

The contiguous outer boundaries of Sullivan County, Tennessee; Washington County, Tennessee; and Washington County, Virginia.

Proposed Amendments to Regulations

If the proposed port of entry designation is adopted, the list of CBP ports of entry at 19 CFR 101.3(b)(1) will be amended to add Tri-Cities, TN/VA, as a port of entry in Tennessee, and "Tri-City Regional Airport" will be deleted from the list of user-fee airports at 19 CFR 122.15(b). Note that the regulations currently refer to the airport as "Tri-City" rather than the correct "Tri-Cities."

Comments

Before adopting this proposal, consideration will be given to any written comments that are timely submitted to CBP. All such comments received from the public pursuant to this notice of proposed rulemaking will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552) and 19 CFR 103.11(b), during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Regulations Branch, Office of Regulations and Rulings, Customs and Border Protection, Department of Homeland Security, 799

9th Street, NW., Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Mr. Joseph Clark at (202) 572-8768. Comments may also be accessed on the EPA Partner EDOCKET Web site or Federal eRulemaking Portal. For additional information on accessing comments via the EPA Partner EDOCKET Web Site or Federal eRulemaking Portal, see the ADDRESSES section of this document.

Authority

This change is proposed under the authority of 5 U.S.C. 301 and 19 U.S.C. 2, 66, and 1624.

The Regulatory Flexibility Act and Executive Order 12866

With DHS approval, CBP establishes, expands and consolidates CBP ports of entry throughout the United States to accommodate the volume of CBP-related activity in various parts of the country. The Office of Management and Budget has determined that this regulatory action is not significant within the meaning of Executive Order 12866. This proposed rule also will not have a significant economic impact on a substantial number of small entities. Accordingly, it is certified that this document is not subject to the additional requirements of the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

Signing Authority

The signing authority for this document falls under 19 CFR 0.2(a) because the establishment of a new port-of-entry and the termination of the user-fee status of an airport are not within the bounds of those regulations for which the Secretary of the Treasury has retained sole authority. Accordingly, this notice of proposed rulemaking may be signed by the Secretary of Homeland Security (or his or her delegate).

Dated: July 25, 2005.

Michael Chertoff,
Secretary.

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA-269P]

Schedules of Controlled Substances: Placement of Embutramide Into Schedule III

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 embutramide, including its salts, into Schedule III 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 III on those who handle embutramide and products containing embutramide.

DATES: Written comments must be postmarked, and electronic comments must be sent, on or before August 29, 2005.

ADDRESSES: To ensure proper handling of comments, please reference "Docket No. DEA-269P" 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 filed 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

Embutramide is a central nervous system depressant drug. On May 20, 2005, the Food and Drug Administration (FDA) approved a New Animal Drug Application (NADA) that provides for veterinary prescription use of Tributame™ Euthanasia Solution containing embutramide, chloroquine phosphate, and lidocaine by intravenous injection for euthanasia of dogs (70 FR 36336). Embutramide as one of the ingredients in the veterinary euthanasia drug product, T-61, was previously marketed in the United States. T-61 was withdrawn from the market in 1991.

Embutramide is a derivative of gamma-hydroxybutyric acid (GHB). Its chemical name is N-[2-(*m*-methoxyphenyl)-2-ethyl-butyl]-gamma-hydroxybutyramide (CAS number 15687-14-6). Embutramide shares pharmacological similarities with other central nervous system (CNS) depressants such as barbiturates, GHB and ketamine. It produces a reversible stupor-like state (narcosis) in experimental animals.

The effects of embutramide on locomotor activity, rearing, forelimb grip strength, hind-limb splay, and the performance of inverted screen tests on rodents were similar to those of pentobarbital. Embutramide produces complete substitution for the pentobarbital discriminative stimulus in mice. Methohexital-trained rhesus monkeys self-administer embutramide.

The pharmacological data suggest that the abuse potential of embutramide may be similar to that of CNS depressants such as barbiturates and their products (Schedules II through IV) and GHB and its product (Schedules I and III) that are controlled under the CSA. Case reports of suicides, attempted suicides, and accidental exposures involving embutramide containing products have been published in the scientific literature. Embutramide is not currently marketed in the United States. From 1998 to 2004, there were no law enforcement encounters of embutramide including seizures or cases.

On January 26, 2005, the Acting Assistant Secretary for Health, DHHS, sent the Deputy Administrator of DEA a scientific and medical evaluation and a letter recommending that embutramide be placed into Schedule III of the CSA. Enclosed with the January 26, 2005, letter was a document prepared by the FDA entitled, "Basis for the Recommendation to Control Embutramide in Schedule III 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 embutramide 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 DEA, the Deputy Administrator of 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, embutramide has a low potential for abuse relative to the drugs or other substances in Schedules I and II;
- (2) Embutramide has a currently accepted medical use in treatment in the United States; and

(3) Abuse of embutramide may lead to moderate or low physical dependence or high psychological dependence.

Based on these findings, the Deputy Administrator of DEA concludes that embutramide warrants control in Schedule III 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 Deputy Administrator, Drug Enforcement Administration, Washington, DC 20537, Attention: DEA **Federal Register** Representative/ODL. 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 Embutramide

If this rule is finalized as proposed, embutramide would be subject to Controlled Substances Act and 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 III controlled substance, including the following:

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

Security. Embutramide 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 embutramide which are distributed 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 embutramide would be required to keep an inventory of all stocks of embutramide 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 III for embutramide 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 embutramide or prescriptions for products containing embutramide would be required to be issued pursuant to 21 CFR 1306.03–1306.06 and 1306.21–1306.27. All prescriptions for embutramide or products containing embutramide issued after publication of the Final Rule, if authorized for refilling, would be limited to five refills.

Importation and Exportation. All importation and exportation of embutramide would need to be in compliance with part 1312 of Title 21 of the Code of Federal Regulations.

Criminal Liability. Any activity with embutramide 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. Embutramide products will be prescription drugs used for the euthanasia of animals. Handlers of embutramide also handle other controlled substances used to euthanize animals 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 section 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 Part 1308 continues to read as follows:

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

2. Section 1308.13 is proposed to be amended by redesignating paragraphs (c)(5) through (c)(13) as paragraphs (c)(6) through (c)(14), and adding a new paragraph (c)(5) to read as follows:

§ 1308.13 Schedule III.

* * * * *

(5) Embutramide XXXX
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Dated: July 22, 2005.
Michele M. Leonhart,
Deputy Administrator.
[FR Doc. 05–15035 Filed 7–28–05; 8:45 am]
BILLING CODE 4410–09–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–149436–04]

RIN 1545–BD92

Return Required by Subchapter T Cooperatives Under Section 6012

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations that prescribe the form that cooperatives must use to file their income tax returns. The regulations affect all cooperatives that are currently required to file an income tax return on either Form 1120, “U.S. Corporation Income Tax Return,” or Form 990–C, “Farmers” Cooperative Association Income Tax Return.”

DATES: Written or electronic comments and requests for a public hearing must be received by October 27, 2005.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–149436–04), room 5203, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to: CC:PA:LPD:PR (REG–149436–04), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC, or sent electronically, via the IRS Internet site at <http://www.irs.gov/regs>, or via the Federal eRulemaking Portal at <http://www.regulations.gov> (IRS–REG–149436–04). A public hearing may be scheduled if requested by any person who timely submits comments.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations,