(b) Payment should be made in the form of a personal, certified, or cashier's check or money order made payable to ''Drug Enforcement Administration.'' Payments made in the form of stamps, foreign currency, or third party endorsed checks will not be accepted. These application fees are not refundable.

Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14286 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–269F]

21 CFR Part 1308

Schedules of Controlled Substances: Placement of Embutramide Into Schedule III

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 embutramide, including its salts, into Schedule III of the Controlled Substances Act (CSA). As a result of this rule, the regulatory controls and criminal sanctions of Schedule III will be applicable to the manufacture, distribution, dispensing, importation and exportation of embutramide and products containing embutramide.

DATES: *Effective Date:* September 28, 2006.

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

SUPPLEMENTARY INFORMATION:

Embutramide has the chemical name of N-[2-(m-methoxyphenyl)-2-ethyl-butyl]-*gamma*-hydroxybutyramide (CAS number 15687–14–6). On May 20, 2005, the Food and Drug Administration (FDA) approved a New Animal Drug Application (NADA) for embutramide for marketing under the trade name Tributame™ Euthanasia Solution (70 FR 36336). This product is a combination of embutramide, chloroquine phosphate, and lidocaine for prescription use by intravenous injection for euthanasia of dogs.

On January 26, 2005, the Acting 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 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))

Similar to barbiturates, embutramide has a central nervous system (CNS) depressant effect. 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, a classical barbiturate. Embutramide mimics discriminative stimulus effects of pentrobarbital in mice. Methohexital-trained rhesus monkeys self-administer embutramide, suggesting that embutramide produces positive reinforcing effects.

The pharmacological data suggest that the abuse potential of embutramide may be similar to that of CNS depressants such as barbiturates and their products (Schedule III through IV) that are controlled under the CSA. Embutramide as one of the ingredients in the veterinary euthanasia drug product T–61, was previously marketed in the United States. T–16 was withdrawn from the market in 1991. Embutramide is not currently marketed in the United States. During the period of marketing of T–61, a limited number of case reports of suicides, attempted suicides, and accidental exposures involving this and similar embutramide containing products were published in the scientific literature. DEA searched, but has not found, any evidence of abuse or trafficking of either T–61 or embutramide.

After a review of the available data, including the scientific and medical evaluation and the scheduling recommendation received from DHHS, the Deputy Administrator of the DEA, in a July 29, 2005, **Federal Register** Notice of Proposed Rulemaking (70 FR 43809), proposed placement of embutramide into Schedule III 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 August 29, 2005.

On August 2, 2005, DEA received a request for an extension of the period in which to comment and request a hearing. The requestor indicated that the additional time was necessary to review the scientific articles and other information cited by DEA in support of its scheduling proposal. DEA granted a 30 day extension of the time to comment and request a hearing, until September 28, 2005 (70 FR 50996).

Comments Received

DEA received two comments in response to the notice of proposed rulemaking. One commenter supported the current proposal to control embutramide as a Schedule III drug. Another commenter supported the proposal to schedule embutramide, the substance, but not its finished pharmaceutical product, Tributame™. This commenter stated that the abuse potential of Tributame™ is non-existent because the negative characteristics such as the presence of a cardiotoxin and the high cost of this formulation outweigh its desirable effects.

DEA does not agree. Careful consideration of all the available data suggests that the amounts of cardiotoxin present in the Tributame™ formulation are insufficient to eliminate the abuse potential of this product. DEA field experience suggests that the cost of a given product is not a consistent predictor of its actual abuse.

DEA also received a request for a hearing on the scheduling of embutramide and a request for an exemption of the product, Tributame™, from scheduling; however, the requestor subsequently withdrew these requests and asked that the scheduling of embutramide be expedited.

Scheduling of Embutramide

Relying on the scientific and medical evaluation and 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, and after a review of the comments received in response to the notice of proposed rulemaking, 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 potential for abuse less than 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, including its salts, warrants control in Schedule III of the CSA. The applicable regulations are as follows:

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, 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 September 28, 2006 and may continue their activities until DEA has approved or denied that application.

Security. Embutramide is subject to Schedule III–V security requirements and must be manufactured, distributed and stored in accordance with Sections 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 on and after September 28, 2006.

Labeling and Packaging. All labels and labeling for commercial containers of embutramide shall comply with requirements of Sections 1302.03–1302.07 of Title 21 of the Code of Federal Regulations and on and after September 28, 2006.

Inventory. Every registrant required to keep records and who possesses any quantity of embutramide must keep an inventory of all stocks of embutramide on hand pursuant to Sections 1304.03, 1304.04 and 1304.11 of Title 21 of the Code of Federal Regulations on and after September 28, 2006. Every registrant who desires registration in Schedule III for embutramide 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 Sections 1304.03, 1304.04, 1304.21, 1304.22, and 1304.23 of Title 21 of the Code of Federal Regulations on and after September 28, 2006.

Prescriptions. All prescriptions for embutramide or prescriptions for products containing embutramide are 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 on and after September 28, 2006, if authorized for refiling, shall, as of that date, be limited to five refills and shall not be refilled after six months of the date is issuance.

Importation and Exportation. All importation and exportation of embutramide must be in compliance with part 1312 of Title 21 of the Code of Federal Regulations on and after September 28, 2006.

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 shall be unlawful on and after September 28, 2006.

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. 56 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. 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.

Embutramide is a new drug in the United States; recent approval of the product and its labeling by the FDA will allow it to be marketed once it is placed into Schedule III of the CSA. This finalrule will allow these entities to have 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 $118,000,000 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 Controlled Substances Act (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

■ 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 1308.13 is 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.

* * * * *

(c) * * *

(5) Embutramide 2020

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Dated: August 22, 2006.

Michele M. Leonhart,

Deputy Administrator.

[FR Doc. E6–14287 Filed 8–28–06; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD05–06–042]

RIN 1625–AA08

Special Local Regulations for Marine Events; Susquehanna River, Port Deposit, MD

AGENCY: Coast Guard, DHS.

ACTION: Notice of enforcement of regulation.

SUMMARY: The Coast Guard will enforce the special local regulations for the ''Ragin' on the River'' powerboat race to be held Labor Day weekend, September 2 and 3, 2006, on the waters of the Susquehanna River, adjacent to Port Deposit, Maryland. This action is necessary to provide for the safety of life on navigable waters during the event. The effect will be to restrict general navigation in the regulated area for the safety of participants and vessels transiting the event area.

DATES: *Effective Dates:* 33 CFR 100.535 will be enforced from 10:30 a.m. to 6:30 p.m. on September 2 and 3, 2006. If the event is postponed due to weather, this section will be enforced during the same time period on Monday, September 4, 2006.

FOR FURTHER INFORMATION CONTACT: Ronald Houck, Coast Guard Sector Baltimore, Prevention Department, at (410) 576–2674.

SUPPLEMENTARY INFORMATION: Annually, during Labor Day weekend, the Port Deposit, Maryland Chamber of Commerce sponsors the ''Ragin' on the River'' powerboat race, on the waters of the Susquehanna River. The event consists of approximately 60 inboard hydroplanes and runabouts racing in heats counterclockwise around an oval racecourse. A fleet of spectator vessels is anticipated to gather nearby to view the competition. Due to the need for vessel control during the event, vessel traffic will be temporarily restricted to provide for the safety of participants, spectators and transiting vessels. In order to ensure the safety of the event participants and transiting vessels, 33 CFR 100.535 will be enforced for the duration of the event. Under provisions of 33 CFR 100.535, a vessel may not enter the regulated area unless it receives permission from the Coast Guard Patrol Commander.

In addition to this notice, the maritime community will be provided extensive advance notification via the Local Notice to Mariners, marine information broadcasts, local radio stations and area newspapers, so mariners can adjust their plans accordingly.

Dated: August 14, 2006.

L.L. Hereth,

Rear Admiral, U.S. Coast Guard, Commander, Fifth Coast Guard District.

[FR Doc. E6–14268 Filed 8–28–06; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R07–OAR–2006–0484; FRL–8213–9]

Approval and Promulgation of Implementation Plans; State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving a State Implementation Plan (SIP) revision submitted by the state of Iowa for the purpose of establishing exemptions for indoor sources of air pollution that are not directly vented to the outside but have emissions that leave the building through doors, vents or other means. This revision also clarifies that the permitting exemptions do not relieve the owner or operator of any source from any obligation to comply with any other applicable requirements. The state has demonstrated that air pollution emissions from this equipment are negligible and these exemptions are likely to result in no significant impact on human health or the environment. We have reviewed the state's justification for the revisions and agree with its conclusions.

DATES: This direct final rule will be effective October 30, 2006, without further notice, unless EPA receives adverse comment by September 28, 2006. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R07–OAR–2006–0484, by one of the following methods:

1. *http://www.regulations.gov.* Follow the on-line instructions for submitting comments.

2. E-mail: *Hamilton.heather@epa.gov.*

3. Mail: Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

4. Hand Delivery or Courier: Deliver your comments to Heather Hamilton, Environmental Protection Agency, Air Planning and Development Branch, 901 North 5th Street, Kansas City, Kansas 66101.

Instructions: Direct your comments to Docket ID No. EPA–R07–OAR–2006–0484. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at *http://www.regulations.gov,* including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Do not submit through *http://www.regulations.gov* or e-mail information that you consider to be CBI or otherwise protected. The *http://www.regulations.gov* Web site is an ''anonymous access'' system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an e-mail comment directly to EPA without going through *http://www.regulations.gov,* your e-mail address will be automatically captured and included as part of the comment that is placed in the public docket and made available on the Internet. If you submit an electronic comment, EPA recommends that you include your name and other contact information in the body of your comment and with any disk or CD–ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses.

Docket: All documents in the electronic docket are listed in the *http://www.regulations.gov* index. Although listed in the index, some information is not publicly available, i.e., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *http://*