

Reporting and recordkeeping requirements.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) by removing the entries for “Carnation Co.”, “Illini Feeds”, and “Tevcon Ind., Inc.” and in the table in paragraph (c)(2) by removing the entries for “047019 and 037310”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.58 [Amended]

4. Section 558.58 *Amprolium and ethopabate* is amended in the table in paragraph (d)(1) by removing paragraph (d)(1)(v).

Dated: August 29, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-22381 Filed 9-5-01; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1313

[DEA-197F]

RIN 1117-AA53

Waiver of Advance Notification Requirement To Import Acetone, 2-Butanone (MEK), and Toluene

AGENCY: Drug Enforcement Administration (DEA), Justice.

ACTION: Final rule.

SUMMARY: This rule finalizes, without change, the Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on October 25, 2000,

(65 FR 63822; as corrected at 65 FR 67796, November 13, 2000) to amend DEA regulations to waive the advance notification requirement to import the solvents acetone, 2-Butanone (MEK), and toluene, which are regulated as List II chemicals. DEA determined that the advance notification requirement is not necessary for these chemicals for effective chemical diversion control. No comments to the NPRM were received. This change to the regulations will ease regulatory burdens for the regulated industry and administrative burdens for DEA.

EFFECTIVE DATE: October 9, 2001.

FOR FURTHER INFORMATION CONTACT: Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307-7297.

SUPPLEMENTARY INFORMATION:

What Does This Final Rule Accomplish?

This final rule finalizes, without change, the Notice of Proposed Rulemaking (NPRM) published in the *Federal Register* on October 25, 2000 (65 FR 63822; as corrected at 65 FR 67796), to amend Title 21, Code of Federal Regulations (CFR) § 1313.12 to waive the advance notification requirement for imports of the solvents acetone, 2-Butanone (MEK), and toluene, which are regulated as List II chemicals. This rule also finalizes a number of technical corrections to the regulations.

By What Authority Is DEA Waiving the Advance Notification Requirement?

The intent of the chemical control provisions of the Controlled Substances Act (CSA) is to curb the diversion of regulated chemicals to the illicit manufacture of controlled substances. This diversion can occur through distribution, importation and exportation of these chemicals. One of the principal components of chemical control with respect to imports and exports is the requirement that advance notification be provided to DEA prior to an importation or exportation of a listed chemical (21 U.S.C. 971). This advance notification allows DEA an opportunity to review the transaction and determine whether it might result in diversion of the chemical to the illicit manufacture of a controlled substance. The advance notification requirement is conditioned by the provision that DEA can waive the requirement for imports or exports of listed chemicals for which the Administrator determines that such advance notification is not necessary for effective chemical diversion control (21

U.S.C. 971(e)(3), 21 CFR 1313.12(c)(2) and 21 CFR 1313.21(c)(2)).

Why Is DEA Waiving the Advance Notification Requirement for Importation of Acetone, 2-Butanone (MEK), and Toluene?

DEA has determined that the advance notification requirement for acetone, 2-Butanone, and toluene is not necessary for effective chemical diversion control and, therefore, is waiving this requirement for these three List II chemicals.

Acetone, 2-Butanone (MEK) and toluene are widely used as industrial chemicals in the United States. The principal concern for DEA in regard to these solvents is their use in the illicit manufacture of cocaine. Cocaine is manufactured overseas; at this time, it is not manufactured in the United States. Diversion of these solvents for illegal manufacture of controlled substances has not been identified as a significant problem in the United States.

What Comments Did DEA Receive Regarding the Proposed Rule?

DEA received no comments to the NPRM.

What Will Be Required for Imports of Acetone, 2-Butanone (MEK), and Toluene?

With waiver of the advance notification requirement, importers of acetone, 2-Butanone (MEK) and toluene will not be required to submit individual DEA Form 486s in advance of each importation. Instead, importers will submit summary quarterly reports of all import transactions as described in 21 CFR 1313.12(e) pursuant to 21 U.S.C. 971(e)(3).

What Is the Impact of This Rulemaking on the Regulatory Burden for the Regulated Industry?

This final rule reduces the paperwork burden for the regulated industry. Approximately two thirds of all 15-day advance notifications of importation (on average 2000 advance notifications annually) are for the solvents acetone, 2-Butanone (MEK), and toluene, equating to an initial paperwork burden reduction of 420 hours. In lieu of this paperwork requirement, DEA is requiring that importers of acetone, 2-Butanone (MEK) and toluene complete a quarterly summary report of all transactions. This quarterly summary report is estimated to impose a regulatory burden of 200 hours per year. Therefore, this change creates a net reduction of 220 annual paperwork burden hours for the regulated industry.

Technical Corrections to the Regulations

DEA also proposed a number of technical corrections to the regulations, which are finalized in this rulemaking.

In 21 CFR 1313.12(b) and 21 CFR 1313.21(b) the reference to the "Drug Control Section" is being changed to the "Chemical Control Section" to reflect organizational changes within DEA. In 21 CFR 1313.21(e), the text noting that no DEA Form 486 is required for exportations subject to 21 CFR 1313.21(c)(2) was inadvertently omitted. This text has been reinserted. Further, an error occurred in 21 CFR 1313.21(e) relating to exports where the word "importation", rather than the word "exportation", was inadvertently used in the sentence: "The report shall contain the following information regarding each individual importation:". The word "exportation" is being substituted to correct this error.

Regulatory Certifications

Regulatory Flexibility Act

The Deputy Assistant Administrator hereby certifies that this rulemaking has been drafted in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation, and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Waiving the 15-day advance notification requirement for imports of acetone, 2-Butanone, and toluene will ease the regulatory burden for the regulated industry.

Executive Order 12866

The Deputy Assistant Administrator further certifies that this rulemaking has been drafted in accordance with the principles in Executive Order 12866 Section 1(b). DEA has determined that this is not a significant regulatory action. This rulemaking will ease regulatory burdens for the regulated industry. Therefore, this action has not been reviewed by the Office of Management and Budget.

Executive Order 12988

This regulation meets the applicable standards set forth in Sections 3(a) and 3(b)(2) of Executive Order 12988.

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.

Paperwork Reduction Act

This rulemaking waives the advance notification requirement for acetone, 2-Butanone and toluene. This change creates a net reduction of 220 annual paperwork burden hours for the regulated industry.

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 \$100,000,000 or more in any one year, and will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the 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.

Plain Language Instructions

The Drug Enforcement Administration makes every effort to write clearly. If you have suggestions as to how to improve the clarity of this regulation, call or write Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, DC 20537, telephone (202) 307-7297.

List of Subjects in 21 CFR Part 1313

Administrative practice and procedure, Drug traffic control, Exports, Imports, List I and List II chemicals, Reporting and recordkeeping requirements.

For the reasons set out above, 21 CFR part 1313 is amended to read as follows:

PART 1313—[AMENDED]

1. The authority citation for part 1313 continues to read as follows:

Authority: 21 U.S.C. 802, 830, 871(b), 971.

2. Section 1313.12 is amended by revising paragraphs (b) and (f) to read as follows:

§ 1313.12 Requirement of authorization to import.

* * * * *

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the importation: Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038.

A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Chemical Control Section, through electronic facsimile media not later than 15 days prior to the importation.

* * * * *

(f) The 15 day advance notification requirement set forth in paragraph (a) has been waived for imports of the following listed chemicals:

- (1) Acetone.
- (2) 2-Butanone (or Methyl Ethyl Ketone or MEK).
- (3) Toluene.

3. Section 1313.21 is amended by revising paragraph (b) and the introductory text of paragraph (e) to read as follows:

§ 1313.21 Requirement of authorization to export.

* * * * *

(b) A completed DEA Form 486 must be received at the following address not later than 15 days prior to the exportation: Drug Enforcement Administration, P.O. Box 28346, Washington, DC 20038. A copy of the completed DEA Form 486 may be transmitted directly to the Drug Enforcement Administration, Chemical Control Section, through electronic facsimile media not later than 15 days prior to the exportation.

* * * * *

(e) For exportations where advance notification is waived pursuant to paragraph (c)(2) of this section, no DEA Form 486 is required, however, the regulated person shall file quarterly reports to the Drug Enforcement Administration, Chemical Control Section, P.O. Box 28346, Washington, DC 20038, by no later than the 15th day of the month following the end of each quarter. The report shall contain the following information regarding each individual exportation:

* * * * *

Dated: August 27, 2001.

Laura M. Nagel,

*Deputy Assistant Administrator, Office of
Diversion Control.*

[FR Doc. 01-22321 Filed 9-5-01; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD09-01-119]

RIN 2115-AE46

Special Local Regulations for Marine Events; Milwaukee River, Milwaukee, WI

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations for the Milwaukee River Challenge crew boat races, an event to be held on the waters of the Milwaukee River, Milwaukee, Wisconsin. These special local regulations are necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in the Milwaukee River, Milwaukee, Wisconsin during the event.

DATES: This rule is effective from 12 m. (noon) until 6 p.m. (local) on September 22, 2001.

ADDRESSES: 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 [CGD09-01-119] and are available for inspection or copying at U.S. Coast Guard Marine Safety Office Milwaukee, 2420 S. Lincoln Memorial Drive, Milwaukee, WI 53207 from 7 a.m. until 3:30 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Timothy Sickler, Port Operations Chief, Marine Safety Office Milwaukee, 2420 South Lincoln Memorial Drive, Milwaukee, WI 53207. The phone number is (414) 747-7155.

SUPPLEMENTARY INFORMATION:

Regulatory Information

A notice of proposed rulemaking (NPRM) was not published 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**. The Coast Guard received the permit request

for special local regulations on August 1, 2001. We were notified of the need for special local regulations with insufficient time to publish an NPRM, allow for comments, and publish a temporary final rule prior to the event on September 22, 2001.

Background and Purpose

On September 22, 2001, Laacke and Joys Inc. will sponsor the Milwaukee River Challenge crew boat races from 12 m. (noon) until 6 p.m. on the waters of the Milwaukee River, Milwaukee, Wisconsin. A fleet of spectator vessels is expected to gather near the event site to view the crew boat races. Normal river traffic will be shut down for a period of six hours between the Chicago Street and Humboldt Avenue bridges. Except for participants in the Milwaukee River Challenge crew boat races and persons or vessels authorized by the Patrol Commander, no person or vessel may enter or remain in the regulated area.

The regulated area for the boat races will encompass all waters of the Milwaukee River and the adjacent shoreline between the Chicago Street and Humboldt Avenue bridges.

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 Transportation (DOT) (44 FR 11040, February 26, 1979).

We expect the economic impact of this temporary final rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary.

Although this regulation prevents traffic from transiting a portion of the Milwaukee River during the event, the effect of this regulation will not be significant due to the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers so mariners can adjust their plans accordingly.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we 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 a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the owners or operators of vessels intending to transit or anchor in the vicinity of the Milwaukee River, Milwaukee, Wisconsin from 12 m. (noon) until 6 p.m. (local) on September 22, 2001.

The effect of this regulation will not be significant because of the limited duration that the regulated area will be in effect and the extensive advance notifications that will be made to the maritime community via the Local Notice to Mariners, marine information broadcasts, and area newspapers so mariners can adjust their plans accordingly.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact U.S. Coast Guard Marine Safety Office Milwaukee. (See **ADDRESSES**.)

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).