

animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Fermenta Animal Health Co. The ANADA provides for the use of a generic gentamicin solution for control of bacterial infections of the uterus (metritis) of horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

**EFFECTIVE DATE:** (September 21, 1995.)

**FOR FURTHER INFORMATION CONTACT:** Sandra K. Woods, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1612.

**SUPPLEMENTARY INFORMATION:** Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, is the sponsor of ANADA 200-023, which provides for the use of a generic gentamicin solution (100 milligrams/milliliter (mg/mL)) for control of bacterial infections of the uterus (metritis) in horses and as an aid in improving conception in mares with uterine infections caused by bacteria sensitive to gentamicin.

ANADA 200-023 for Fermenta Animal Health Co.'s gentamicin sulfate solution (100 mg/mL gentamicin) is approved as a generic copy of Schering's Gentocin® Solution (100mg/mL gentamicin) in NADA 046-724. The ANADA is approved as of August 4, 1995, and the regulations are amended in 21 CFR 529.1044a to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

#### List of Subjects in 21 CFR Part 529

Animal drugs.

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 part 529 is amended to read as follows:

#### **PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS**

1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

##### **§ 529.1044a [Amended]**

2. Section 529.1044a *Gentamicin sulfate intrauterine solution* is amended in paragraph (b) by removing "000061, 000856, 057561, and 058711" and adding in its place "000061, 000856, 054273, 057561, and 058711".

Dated: September 5, 1995.

Stephen F. Sundlof,

*Director, Center for Veterinary Medicine.*

[FR Doc. 95-23353 Filed 9-20-95; 8:45 am]

BILLING CODE 4160-01-F

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## DEPARTMENT OF THE INTERIOR

### Bureau of Indian Affairs

#### 25 CFR Part 151

RIN 1076-AC51

#### Land Acquisitions (Nongaming)

**AGENCY:** Bureau of Indian Affairs, Interior.

**ACTION:** Final rule: correction.

**SUMMARY:** This document contains corrections to the final rule 25 CFR Part 151, which was published Friday, June 23, 1995, (Vol. 60, No. 121, FR 32874-32879). The regulations related to land acquisitions for nongaming purposes by an Indian individual or tribe.

**EFFECTIVE DATE:** September 21, 1995.

**FOR FURTHER INFORMATION CONTACT:**

Alice A. Harwood, Chief, Branch of Technical Services, Division of Real Estate Services, Bureau of Indian Affairs, Room 4522, Main Interior Building, 1849 C Street, NW, Washington, DC 20240, Telephone No. (202) 208-3604.

**SUPPLEMENTARY INFORMATION:**

#### Background

The final rule that is the subject of these corrections modified three existing sections within Part 151 (Land Acquisitions) and created a new section

which contained additional criteria and requirements used by the Secretary in evaluating requests for the acquisition of lands by the Untied States in trust for federally recognized Indian tribes when lands are outside and noncontiguous to the tribe's existing reservation boundaries.

#### Need for Correction

As published, the final rule contains errors which may prove to be misleading and are in need of clarification.

#### Correction of Publication

Accordingly, the publication on June 23, 1995, of the final rule (25 CFR 151), FR Doc. 95-15215, is corrected as follows:

#### **Part 151—LAND ACQUISITIONS (NONGAMING)**

On page 32878, third column, in the title, delete "(Nongaming)".

##### **§ 151.11 [Amended]**

On page 32879, in the second column, in § 151.11, add "(Nongaming)" after "acquisitions" in the title.

On page 32879, in the second column, in § 151.11, line four of paragraph (b), insert "as follows:" after the word "considered."

On page 32879, in the second column, in § 151.11, line three of paragraph (d), insert "as follows:" after the word "completed."

Dated: September 7, 1995.

Ada E. Deer,

*Assistant Secretary—Indian Affairs.*

[FR Doc. 95-23010 Filed 9-20-95; 8:45 am]

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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[CGD13-95-039]

#### **Safety Zone Regulation; Trojan Nuclear Plant, Rainier, OR, to Port of Benton, WA**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Temporary final rule.

**SUMMARY:** The Coast Guard is establishing a moving safety zone around the barge ZB-1801 and accompanying towboats as the vessels complete five separate transits through U.S. navigable waters between Rainier, Oregon, and Benton, Washington. A safety zone is needed to protect the barge ZB-1801 and accompanying

towboats, persons, facilities, and other vessels from safety hazards associated with onlookers and others who may wish to view the barge at close range. Entry into the safety zone is prohibited unless authorized by the Captain of the Port.

**EFFECTIVE DATE:** This regulation becomes effective on September 20, 1995 at 12 a.m. (PDT) and will terminate on November 19, 1995 at 12 p.m. (PST), unless sooner terminated by the Captain of the Port.

**FOR FURTHER INFORMATION CONTACT:** LTJG C. A. Roskam, c/o U.S. Coast Guard Captain of the Port, 6767 N. Basin Ave., Portland, Oregon 97217-3992, Ph: (503) 240-9338.

**SUPPLEMENTARY INFORMATION:** In accordance with 5 U.S.C. 553, a Notice of Proposed Rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days after Federal Register publication. Specific final details regarding the schedule of the barge movements were not available in sufficient time to allow for the publication of a Notice of Proposed Rulemaking. Publishing a Notice of Proposed Rulemaking and delaying this regulation's effective date would be contrary to the public interest since immediate action is needed to prevent potential hazards to the barge ZB-1801 and other vessels that may transit the area. For these reasons, normal rulemaking procedures would have been impracticable.

#### Drafting Information

The drafters of this regulation are LTJG C. A. Roskam, Project Officer for the Captain of the Port, and LCDR John C. Odell, Project Attorney, Thirteenth Coast Guard District Legal Office.

#### Discussion of Regulation

The event requiring this regulation will begin on September 20, 1995 at 2 p.m. (PDT). Upon request of the Portland General Electric Company, the Coast Guard is establishing a moving safety zone consisting of all navigable waters within 100 yards of the barge ZB-1801 and accompanying towboats. While this safety zone is in effect, these vessels are expected to complete five separate round-trip transits on the Columbia River from the Trojan Nuclear Plant in Rainier, Oregon, to the Port of Benton, Washington. The safety zone will be in effect at all times while the barge is being loaded at the Trojan Nuclear Plant, while the barge and accompanying towboats transit from the Trojan Nuclear Plant to the Port of Benton, while the barge is unloaded at

the Port of Benton, and during the barge's return transits to the Trojan Nuclear Plant. Thus, the safety zone remains in effect for the duration of the five transits, each of which may result in a large number of vessels congregating near, or in the path of the barge and towboats. This safety zone is needed due to the limited maneuverability of the barge and towboats, as well as the need to ensure the safety of mariners who may attempt to approach the barge and towboats during loading, unloading, and transiting. This moving safety zone will be enforced by representatives of the Captain of the Port, Portland, Oregon. The Captain of the Port may be assisted by other federal agencies.

#### Regulatory Evaluation

This temporary final rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential cost and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040, February 26, 1979). The Coast Guard expects the economic impact of this proposal to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This expectation is based on the relatively short duration of the safety zone and the small geographic area affected.

#### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard was required to consider whether this action would have a significant economic impact on a substantial number of small entities. "Small entities" may include (1) small businesses and not-for-profit organizations that are independently owned and operated and are not dominant in their fields and (2) governmental jurisdictions with populations of less than 50,000. Because it expects the impact of this action to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this action will not have a significant economic impact on a substantial number of small entities.

#### Collection of Information

This action contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

#### Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Environment

The Coast Guard considered the environmental impact of this action and concluded that, under paragraph 2.B.2.c. of Commandant Instruction M16475.1B, this action is categorically excluded from further environmental documentation. A Categorical Exclusion Determination statement has been prepared and placed in the rulemaking docket.

#### List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

#### Temporary Regulation

For the reasons set out in the preamble, the Coast Guard amends subpart C of part 165 of title 33, Code of Federal Regulations, as follows:

#### **PART 165—[AMENDED]**

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; 49 CFR 1.46.

2. A new section 165.T13-036 is added to read as follows:

#### **§ 165.T13-036 Safety zone: COTP Portland, Oregon.**

(a) *Location.* The following area is a safety zone: All waters within 100 yards of the barge ZB-1801 and accompanying towboats during the loading of the barge ZB-1801 at the Trojan Nuclear Plant, and while in transit from the Trojan Nuclear Plant, Rainier, Oregon, to the Port of Benton, Washington. The safety zone continues while the barge is unloaded at the Port of Benton, and remains in effect during the barge's return transits to the Trojan Nuclear Plant. The barge and accompanying towboats will make approximately five round-trip transits between the Trojan Nuclear Plant and the Port of Benton during the time this safety zone is in effect.

(b) *Definitions.* A designated representative of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer who has been authorized by the Captain of the Port Portland, to act on his behalf. The

following officers have or will be designated by the Captain of the Port: the Coast Guard Patrol Commander, the senior boarding officer on each vessel enforcing the safety zone, and the Duty Officer at Coast Guard Group Portland, Oregon.

(c) *Regulations.* In accordance with the general regulations in Section 165.23 of this part, entry into this zone is prohibited, unless authorized by the Captain of the Port or his designated representatives.

(d) *Effective Dates.* This section is effective on September 20, 1995 at 12 a.m. (PDT), and remains in effect until November 19, 1995 at 12 p.m. (PST), unless sooner terminated by the Captain of the Port.

Dated: August 29, 1995.

C.E. Bills,

*Captain, U.S. Coast Guard, Captain of the Port.*

[FR Doc. 95-23354 Filed 9-20-95; 8:45 am]

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 52

[IL98-2-6840; FRL-5299-3]

#### Approval and Promulgation of an Implementation Plan for Vehicle Miles Traveled; Illinois

**AGENCY:** Environmental Protection Agency.

**ACTION:** Final rule.

**SUMMARY:** The United States Environmental Protection Agency (USEPA) is approving a request from Illinois, for a State Implementation Plan (SIP) revision for the Chicago ozone nonattainment area, which demonstrates how mobile source emissions will continue to decline over the years and not increase. In addition, Illinois has implemented 127 transportation control measures (TCMs) for a total reduction of more than two tons per day of volatile organic compounds. Two public comment letters were received which are addressed in this rulemaking. This rulemaking action approves, in final, the first two requirements of the vehicle miles traveled (VMT) Offset SIP revision request and the associated TCMs for Chicago, Illinois as requested by Illinois.

**EFFECTIVE DATE:** This final rule is effective on October 23, 1995.

**ADDRESSES:** Copies of the documents relevant to this action are available for inspection during normal business hours at the following location:

Regulation Development Section, Regulation Development Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois, 60604.

Please contact Patricia Morris at (312) 353-8656 before visiting the Region 5 office.

**FOR FURTHER INFORMATION CONTACT:** Patricia Morris, Regulation Development Section, Regulation Development Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 353-8656.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

Section 182(d)(1)(A) of the Clean Air Act, as amended in 1990 (Act), requires States containing ozone nonattainment areas classified as "severe" pursuant to section 181(a) of the Act to adopt TCMs and transportation control strategies to offset any growth in emissions from growth in VMT or number of vehicle trips, and to attain reductions in motor vehicle emissions (in combination with other emission reduction requirements) as necessary to comply with the Act's RFP milestones and attainment requirements. The requirements for establishing a VMT Offset program are discussed in the April 16, 1992, General Preamble to Title I of the Act (57 FR 13498), in addition to section 182(d)(1)(A) of the Act.

The VMT Offset provision requires that States submit by November 15, 1992, specific enforceable TCMs and strategies to offset any growth in emissions from growth in VMT or number of vehicle trips sufficient to allow total area emissions to comply with the RFP and attainment requirements of the Act.

As described in the November 2, 1994, proposed rule (see 59 FR 54866, 54867), the USEPA has observed that these three elements (i.e., offsetting growth in mobile source emissions, attainment of the RFP reduction, and attainment of the ozone National Ambient Air Quality Standards (NAAQS)) can be divided into three separate submissions that could be submitted on different dates.

Under this approach, the first element, the emissions offset element, was due on November 15, 1992. The USEPA believes this element is not necessarily dependent on the development of the other elements. The State could submit the emissions growth offset element independent of an analysis of that element's consistency with the periodic reduction and attainment requirements of the Act.

Emissions trends from other sources need not be considered to show compliance with this offset requirement. As submitting this element in isolation does not implicate the timing problem of advancing deadlines for RFP and attainment demonstrations, USEPA does not believe it is necessary to extend the statutory deadline for submittal of the emissions growth offset element.

The second element, which requires the VMT Offset SIP to comply with the 15 percent RFP requirement of the Act, was due on November 15, 1993, which is the same date on which the 15 percent RFP SIP itself was due under section 182(b)(1) of the Act. The USEPA believes it is reasonable to extend the deadline for this element to the date on which the entire 15 percent SIP was due, as this allows States to develop the comprehensive strategy to address the 15 percent reduction requirement and assure that the TCM elements required under section 182(d)(1)(A) are consistent with the remainder of the 15 percent demonstration. Indeed, USEPA believes that only upon submittal of the broader 15 percent plan can a State have had the necessary opportunity to coordinate its VMT strategy with its 15 percent plan.

The third element, which requires the VMT Offset SIP to comply with the post-1996 RFP and attainment requirements of the Act, was due on November 15, 1994, the statutory deadline for those broader submissions. The USEPA believes it is reasonable to extend the deadline for this element to the date on which the post-1996 RFP and attainment SIPs are due for the same reasons it is reasonable to extend the deadline for the second element. First, it is arguably impossible for a State to make the showing required by Section 182(d)(1)(A) for the third element until the broader demonstrations have been developed by the State. Moreover, allowing States to develop the comprehensive strategy to address post-1996 RFP and attainment by providing a fuller opportunity to assure that the TCM elements comply with the broader RFP and attainment demonstrations, will result in a better program for reducing emissions in the long term.

On July 14, 1994, Illinois submitted to USEPA documentation to fulfill the VMT-Offset SIP. A public hearing was held on June 22, 1994, and documentation on the public hearing was submitted to complete the SIP revision request. The SIP revision was found to be complete by the USEPA in a letter dated August 4, 1994. The USEPA proposed to approve the first and second element on December 4,