
Thursday
September 21, 1995

Federal Register

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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

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 United 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]

BILLING CODE 4310-02-M

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