

(3) * * * For use in preruminating calves including veal calves only, not for use in other animals which are raised for food production. * * *

3. Section 520.88e is amended by revising the heading for paragraph (d), paragraph (d)(2), and the first sentence in paragraph (d)(3) to read as follows:

§ 520.88e Amoxicillin trihydrate boluses.

* * * * *

(d) *Conditions of use. Preruminating calves including veal calves—*

* * * * *

(2) *Indications for use.* Treatment of bacterial enteritis when due to susceptible *Escherichia coli* in preruminating calves including veal calves.

(3) *Limitations.* For oral use in preruminating calves including veal calves only, not for use in other animals which are raised for food production.

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Dated: January 27, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug
Evaluation Center for Veterinary Medicine
[FR Doc. 97-3015 Filed 2-5-97; 8:45 am]

BILLING CODE 4160-01-F

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Tilmicosin Phosphate Injection

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Elanco Animal Health, a Division of Eli Lilly and Co. The supplemental NADA provides for subcutaneous use of tilmicosin phosphate injection for the control of respiratory disease in cattle at high risk of developing bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*.

EFFECTIVE DATE: February 6, 1997.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1659.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, is sponsor of NADA 140-929, which provides for the subcutaneous use of Micotil® 300 (tilmicosin phosphate) Injection for the

treatment of cattle with bovine respiratory disease (BRD) associated with *P. haemolytica*. The drug is limited to use by or on the order of a licensed veterinarian. The firm filed a supplemental NADA, which provides for use of Micotil® for the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*. The supplement is approved as of December 30, 1996, and 21 CFR 522.2471(d)(1)(ii) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, certain limitation statements for use of the product are revised to reflect current wording. Section 522.2471(d)(1)(iii) is amended by revising two sentences.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning December 30, 1996, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety, or, in the case of food producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new claim, control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*, for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that this 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

21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.2471 is amended by revising paragraph (d)(1)(ii) and the last four sentences of paragraph (d)(1)(iii) to read as follows:

§ 522.2471 Tilmicosin phosphate injection.

* * * * *

(d) * * *

(1) * * *

(ii) *Indications for use.* For the treatment of bovine respiratory disease (BRD) associated with *Pasteurella haemolytica*. For the control of respiratory disease in cattle at high risk of developing BRD associated with *P. haemolytica*.

(iii) * * * A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal. Do not slaughter within 28 days of last treatment. Federal law restricts this drug to use or on the order of a licensed veterinarian.

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Dated: January 27, 1997.

Robert C. Livingston,

Director, Office of New Animal Drug
Evaluation Center for Veterinary Medicine
[FR Doc. 97-3016 Filed 2-5-97; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[COTP San Juan 96-077]

RIN 2115-AA97

Safety Zone Regulations: Southeast End of Vieques Island, PR

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone on the

southeast end of Vieques Island during small boat operations and testing conducted by the U.S. Navy. This safety zone will remain in effect for all vessels during the following times: from 5 p.m. until 6 a.m. local time, between February 5 to February 9, 1997, and from 5 p.m. until 6 a.m. local time, between February 11, to February 15, 1997. The U.S. Navy will be testing vessels at high speed in the safety zone. Therefore, these regulations are necessary to provide for the safety of life on navigable waters during the naval operations. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATES: This regulation becomes effective on January 31, 1997, at 5 p.m. local time. The safety zone will terminate on February 15, 1997 at 6 a.m. local time.

FOR FURTHER INFORMATION CONTACT:

Lieutenant Junior Grade M.J. Simbulan or Ensign Jose A. Pena at (787) 729-6800, ext. 380/381, Marie Safety Office, San Juan, P.O. Box 9023666, San Juan, PR 00902-3666.

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. Publishing an NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to minimize the potential for hazards to the vessels affected and the environment. The information on this event was received within sufficient time to publish proposed rules in advance or provide for a delayed effective date.

Discussion of Regulations

The Coast Guard is establishing a safety zone on the southeast end of Vieques Island during small boat operations and testing conducted by the U.S. Navy. This safety zone will remain in effect for all vessels during the following times: from 5 p.m. until 6 a.m. local time, between January 31 to February 4, 1997, from 6:30 a.m. until 4 p.m. local time, between February 5 to February 9, 1997, and from 5 p.m. until 6 a.m. local time, between February 11 to February 15, 1997. The U.S. Navy will be testing vessels at high speed in the safety zone. Therefore, these regulations are necessary to provide for the safety of life on navigable waters during the naval operations. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

The safety zone will encompass an area of approximately 13 square miles. The safety zone extends northward from latitude 18-05.0 N to the South coast of Vieques Island or latitude 18-08.0 N. The safety zone is bound on the east by longitude 065-21.0 W and on the west by longitude 065-16.0 W. This regulation is issued pursuant to 33 U.S.C. 1225 and 1231 as set out in the authority citation for all of Part 165.

Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has not been reviewed by the Office of Management and Budget 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). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This safety zone will be effective for a limited number of days and affect a small area.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider the economic impact on small entities of a rule for which a general notice of proposed rulemaking is required. "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 jurisdiction with populations of less than 50,000. The Coast Guard certifies that this rule will not have a significant economic impact on a substantial number of small entities because the regulation will be effective for a limited number of days and affect a limited area.

Collection of Information

This rule contain 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 the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this proposal consistent with Section 2.B.2. of Commandant Instruction M16475.1B, (as revised by 59 FR 38654, July 29, 1994), this rule is categorically excluded from further environmental documentation. In accordance with section 2.B.2.e.(34)(g), the Coast Guard has completed an Environmental Impact Determination and a Categorical Exclusion Checklist.

List of Subjects in 33 CFR Part 165

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

Temporary Regulations

In consideration of the foregoing, Subpart C of Part 165 of title 33, Code of Federal Regulations, the Coast Guard amends 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 165.T96-077 is added to read as follows:

§ 165.T96-077 Safety Zone: Southeast end of Vieques Island, PR.

(a) *Location.* The following area is a safety zone:

A four-sided box bounded on the north by the south shore of Vieques or latitude 18-08.0 N, bounded on the south by latitude 18-05.0 N, bounded on the east by longitude 65-16.0 W, and bounded on west by longitude 65-21.0 W.

(b) *Effective date.* This regulation becomes effective at 5 p.m. local time on 31 January 1997. It will terminate at approximately 6 a.m. local time on 15 February 1997, unless terminated sooner by the Coast Guard Captain of the Port.

(c) *Regulations.* In accordance with the general regulations in § 165.23 of this part, entry into this zone is prohibited unless authorized by the Coast Guard Captain of the Port.

Dated: January 24, 1997.

B.M. Salerno,
Commander, U.S. Coast Guard, Captain of the Port, San Juan, Puerto Rico.

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