(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. * * *

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 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.

* * * * *

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]

BILLING CODE 4160–01–F

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