DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tiamulin

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 Boehringer Ingelheim Vetmedica, Inc. The supplemental NADA provides for use of approved tiamulin Type A medicated articles to make Type B and Type C medicated feeds used for the control of porcine proliferative enteropathies (ileitis) in swine.

DATES: This rule is effective February 19, 2002.

FOR FURTHER INFORMATION CONTACT: Diane D. Jeang, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7574, e-mail: djeang@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Boehringer Ingelheim Vetmedica, Inc., 2621 North Belt Highway, St. Joseph, MO 64506–2002, filed a supplement to approved NADA 139–472 that provides for use of DENAGARD (5, 10, or 113.4 grams (g) per pound of tiamulin) Type A medicated articles to make Type B and Type C medicated feeds for use in growing and finishing swine. The Type C medicated feeds contain 35 g per ton tiamulin and are used for the control of porcine proliferative enteropathies (ileitis) associated with *Lawsonia intracellularis*. The NADA is approved as of November 26, 2001, and § 558.600 (21 CFR 558.600) is amended to reflect the approval. Section 558.600 is also being revised to a tabular format. The basis for approval is discussed in the freedom of information summary.

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, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, 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 on November 26, 2001, because the 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 the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new claim for which the supplemental application was approved.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

2. Section 558.600 is revised to read as follows:

§ 558.600 Tiamulin.

(a) *Specifications*. Type A article containing 5, 10, or 113.4 grams of tiamulin (as tiamulin hydrogen fumarate) per pound.

(b) *Approvals*. See No. 000010 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.738 of this chapter.

(d) *Special considerations*—(1) Swine being treated with tiamulin should not have access to feeds containing polyether ionophores (e.g., lasalocid, monensin, narasin, salinomycin, or semduramycin) as adverse reactions may occur. If signs of toxicity occur, discontinue use.

(2) Not for use in swine weighing over 250 pounds.

(3) Use as sole source of tiamulin.

(e) *Conditions of use*—(1) *Swine*. It is used as follows:

Tiamulin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 10		For increased rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration.	000010
(ii) 35		1. For control of swine dysentery associated with*Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as sole ration on premises with a history of swine dysentery but where signs of disease have not yet occurred or following approved treatment of disease. Withdraw 2 days before slaughter.	000010
		2. For control of porcine proliferative enteropathies (ileitis) associated with*Lawsonia intracellularis*.	Feed continuously as the sole ration for not less than 10 days. Withdraw 2 days before slaughter.	000010

Tiamulin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(iii) 35	Chlortetracycline, approximately 400 (varying with body weight and feed consumption to provide 10 milligrams of chlortetracycline per pound of body weight daily).	For treatment of swine bacterial enteritis caused by*Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida* susceptible to chlortetracycline, and control of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as sole ration for 14 days. Use as only source of chlortetracycline. Withdraw 2 days before slaughter. As chlortetracycline calcium complex, Type A medicated articles containing the equivalent of 50 to 100 grams per pound of chlortetracycline hydrochloride provided by 046573 and 053389 in §510.600(c) of this chapter.	000010
(iv) 200	.....	For treatment of swine dysentery associated with *Brachyspira* (formerly *Serpulina* or *Treponema*) *hyodysenteriae* susceptible to tiamulin.	Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter.	000010

(2) [Reserved]

Dated: January 31, 2002.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

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DEPARTMENT OF JUSTICE

28 CFR Part 65

[OJP(BJA)–1334]

RIN 1121–AA60

Bureau of Justice Assistance; Emergency Federal Law Enforcement Assistance

AGENCY: Office of Justice Programs, Bureau of Justice Assistance, Justice.

ACTION: Final rule; correction.

SUMMARY: This rule corrects the address for submission of applications to the Director, Bureau of Justice Assistance, U.S. Department of Justice, for the Emergency Federal Law Enforcement Assistance (EFLEA) Program. This correction reflects a change of address for the Director, Bureau of Justice Assistance, Office of Justice Program, U.S. Department of Justice.

EFFECTIVE DATE: This change will be effective upon publication in the **Federal Register**.

FOR FURTHER INFORMATION CONTACT: Linda Fallowfield or Victoria O'Brien at 202–307–6235.

SUPPLEMENTARY INFORMATION: The Bureau of Justice Assistance is issuing this final rule to correct the address to which a state or local unit of government may submit applications for the Emergency Federal Law Enforcement Assistance Program. The purpose of this program is to provide assistance to an uncommon situation which is or threatens to escalate to serious or epidemic proportions and state or local resources are not sufficient to protect the lives and property of citizens, or to enforce the criminal law.

Currently, the state must submit the application directly to the Attorney General, U.S. Department of Justice with one copy to the Director, Bureau of Justice Assistance, Office of Justice Programs, U.S. Department of Justice. The Office of Justice Programs has moved to a different location in Washington, DC necessitating this correction to the regulation.

Regulatory Certifications

Executive Order 12866

This regulation has been written and reviewed in accordance with Executive Order 12866, Sec. 1(b), Principles of Regulation. The Office of Justice Programs has determined that this rule is not a ''significant regulatory action'' under Executive Order 12866, Sec. 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by the Office of Management and Budget.

Executive Order 12612

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act

The Office of Justice Programs, 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 upon a substantial number of small entities for the following reasons: The EFLEA program is administered by the Office of Justice Programs. The economic impact is limited to the Office of Justice Program's appropriated funds.

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 it 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 Sec. 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 cost 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.