

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.

DMB

Dis: [unclear]	2-15-02
Pub: [unclear]	2-19-02
Cert: [unclear]	N. Hawkins

0166 02 FEB 14 13:41

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 [*insert date of publication in the Federal Register*].

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.

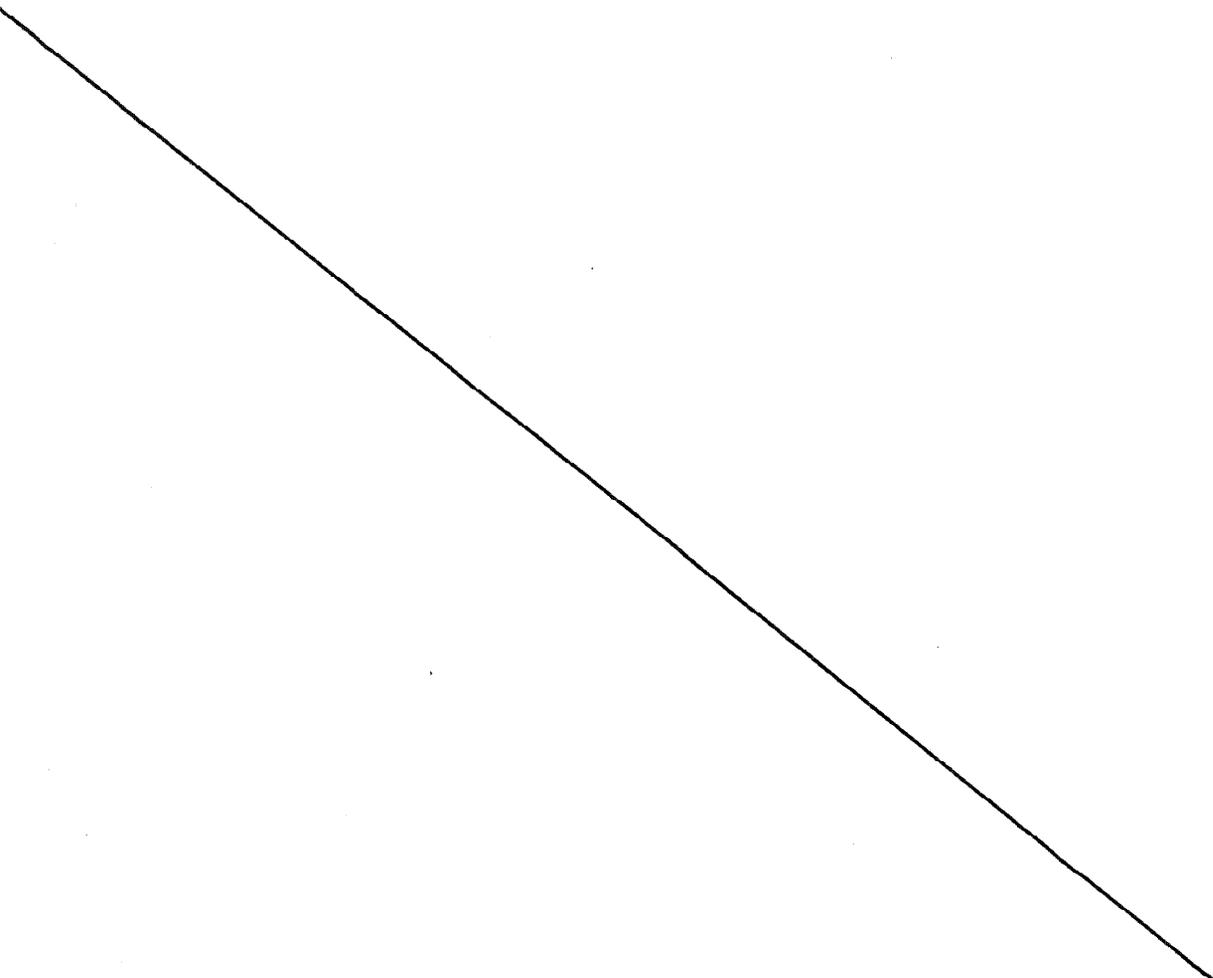
(3) Use as sole source of tiamulin.

(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 <i>Brachyspira</i> (formerly <i>Serpulina</i> or <i>Treponema</i>) <i>hyodysenteriae</i> 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 <i>Lawsonia intracellularis</i> .	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 <i>Escherichia coli</i> and <i>Salmonella choleraesuis</i> and bacterial pneumonia caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline, and control of swine dysentery associated with <i>Brachyspira</i> (formerly <i>Serpulina</i> or <i>Treponema</i>) <i>hyodysenteriae</i> 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 <i>Brachyspira</i> (formerly <i>Serpulina</i> or <i>Treponema</i>) <i>hyodysenteriae</i> susceptible to tiamulin.	Feed continuously as the sole feed for 14 consecutive days. Withdraw feed 7 days before slaughter.	000010

(2) [Reserved]



Dated: 1/31/02
January 31, 2002.

cv0128

Claire M Lathers

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

[FR Doc. 01-00000 Filed 01-31-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL

Dawn P. Hawkins