

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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Certifier G. Trenley

New Animal Drugs for Use in Animal Feeds; Lincomycin

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 Pharmacia & Upjohn Co. The supplemental NADA provides for the use of lincomycin in swine feed for the control of porcine proliferative enteropathies (ileitis).

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Steven D. Vaughn, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7584, e-mail: svaughn@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pharmacia & Upjohn Co., 7000 Portage Rd., Kalamazoo, MI 49001-0199, filed a supplement to NADA 97-505 that provides for use of LINCOMIX 20 (lincomycin hydrochloride) and LINCOMIX 50 Feed Medications in medicated swine feeds for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis*. The supplemental application is approved as of February 28, 2002, and the regulations are amended in 21 CFR 558.325 to reflect the approval. Section 558.325 is also being revised to reflect a current format.

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 supplemental application may be seen in the Dockets Management Branch (HFA-

cv01106

NADA 97-505

NFR 1

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 qualifies for 3 years of marketing exclusivity beginning February 28, 2002, 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 approval of the application and conducted or sponsored by the applicant.

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 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 558.325 is amended in paragraph (a) by removing “paragraph (c)” and in its place adding “paragraph (d)”; by revising paragraphs (a)(1), (a)(5), and (a)(13); in paragraph (b) by removing “*in edible products*”; and by revising paragraph (d) to read as follows:

§ 558.325 Lincomycin.

(a) * * *

(1) No. 000009 for 20 and 50 grams per pound.

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(5) No. 043733 for 8 and 20 grams per pound.

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(13) No. 017800 for 2.5 and 8 grams per pound.

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(d) *Conditions of use*—(1) *Chickens*. It is used in feed as follows:

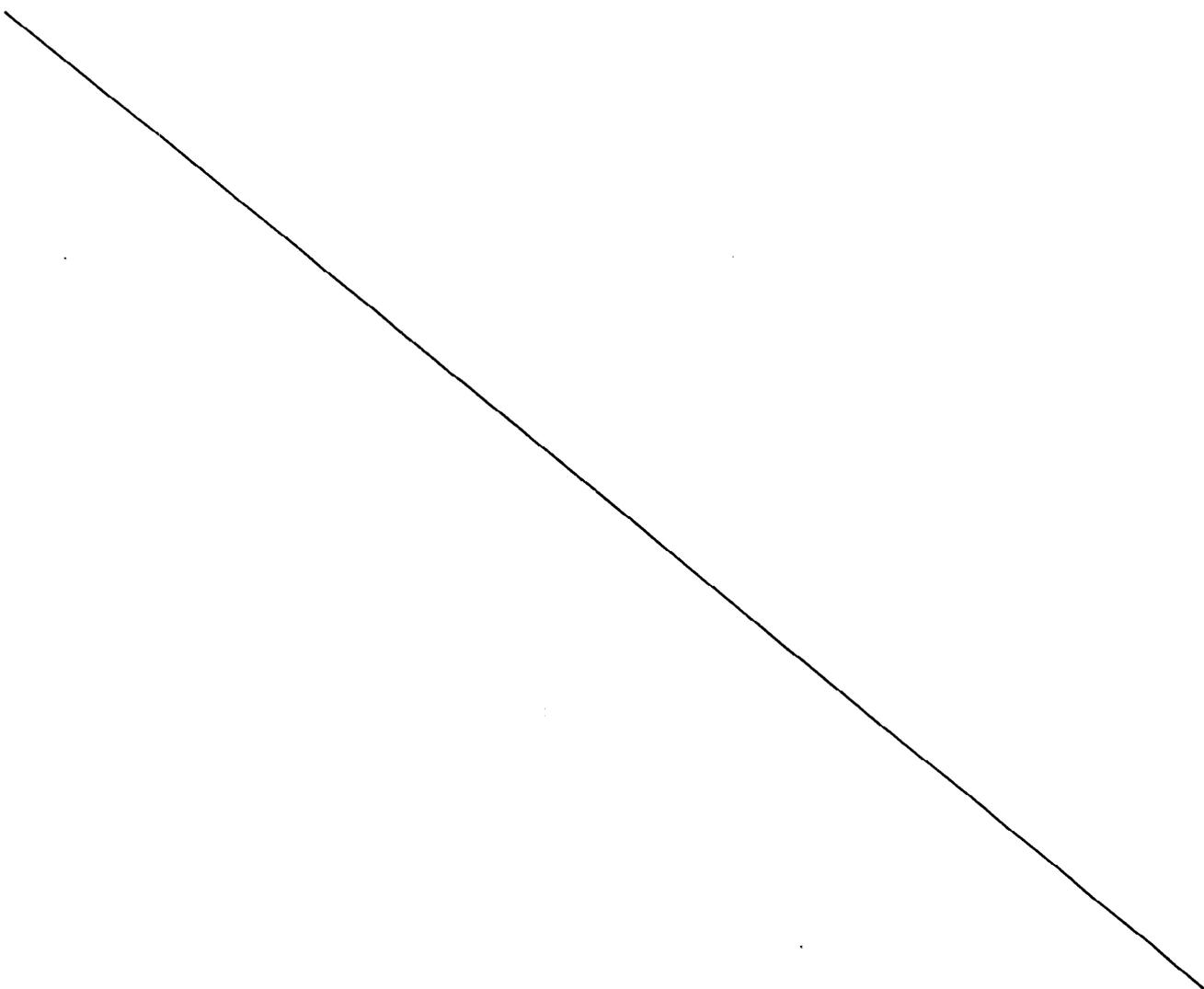
Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 2	Broilers: For control of necrotic enteritis caused by <i>Clostridium</i> spp. or other susceptible organisms.	As lincomycin hydrochloride monohydrate.	000009
(ii) 2 to 4	Broilers: For increased rate of weight gain and improved feed efficiency.	As lincomycin hydrochloride monohydrate.	000009

(2) *Swine*. It is used in feed as follows:

Lincomycin grams/ton	Indications for use	Limitations	Sponsor
(i) 20	Growing-finishing swine: For increased rate of weight gain.	Feed as sole ration. Not to be fed to swine that weigh more than 250 pounds (lb).	000009
(ii) 40	1. For control of swine dysentery.	Feed as sole ration; for use in swine on premises with a history of swine dysentery but where symptoms have not yet occurred, or following use of lincomycin at 100 grams (g)/ton for treatment of swine dysentery. Not to be fed to swine that weigh more than 250 lb.	000009 017800 043733
	2. For control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as sole ration, or following use of lincomycin at 100 g/ton for control of porcine proliferative enteropathies (ileitis). Not to be fed to swine that weigh more than 250 lb.	000009
(iii) 100	1. For treatment of swine dysentery.	Feed as sole ration for 3 weeks or until signs of disease disappear. Not to be fed to swine that weigh more than 250 lb.	000009 017800 043733
	2. For control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> .	Feed as sole ration for 3 weeks or until signs of disease disappear. Not to be fed to swine that weigh more than 250 lb.	000009
(iv) 200	For reduction in the severity of swine mycoplasmal pneumonia caused by <i>Mycoplasma hyopneumoniae</i> .	Feed as sole ration for 3 weeks. Not to be fed to swine that weigh more than 250 lb.	000009 017800

(3) Lincomycin may also be used in combination with:

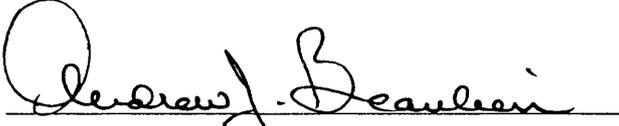
(i) Amprolium and ethopabate or amprolium and ethopabate with roxarsone in accordance with § 558.58.

- (ii) Clopidol in accordance with § 558.175.
 - (iii) Decoquinatate in accordance with § 558.195.
 - (iv) Fenbendazole as provided in § 558.258.
 - (v) Halofuginone in accordance with § 558.265.
 - (vi) Ivermectin as in § 558.300.
 - (vii) Lasalocid alone or with roxarsone in accordance with § 558.311.
 - (viii) Monensin alone or with roxarsone in accordance with § 558.355.
 - (ix) Nicarbazin alone or with narasin or roxarsone as in § 558.366.
 - (x) Pyrantel as in § 558.485.
 - (xi) Robenidine in accordance with § 558.515.
 - (xii) Roxarsone in accordance with § 558.530.
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(xiii) Salinomycin with or without roxarsone as in § 558.550.

(xiv) Zoalene in accordance with § 558.680.

Dated: May 14, 2002
May 14, 2002.



Andrew J. Beaulieu
Acting Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

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