

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazin and Bacitracin Zinc

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 new animal drug application (NADA) filed by Koffolk, Inc. The NADA provides for using approved nicarbazin and bacitracin zinc Type A medicated articles to make combination Type C medicated broiler chicken feeds used for prevention of coccidiosis and for increased rate of weight gain and improved feed efficiency.

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

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Koffolk, Inc., P.O. Box 675935, 14735 Las Quintas, Rancho Santa Fe, CA 92067, filed NADA 141-146 that provides for combining approved Nicarb® (113.5 grams per pound (g/lb) nicarbazin) manufactured by Koffolk, Inc., and Baciferm® (50 g/lb bacitracin as bacitracin zinc) manufactured by Roche Vitamins, Inc., Type A medicated articles to make Type C medicated broiler chicken feeds. The Type C broiler feeds contain 113.5 g/ton (t) nicarbazin and 4 to 50 g/t bacitracin. The Type C broiler chicken feeds are used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, and for increased rate of weight gain and improved feed efficiency.

The NADA is approved as of February 2, 2000, and the regulations are amended by adding 21 CFR 558.78(d)(3)(xxi) and by amending the table in 21 CFR 558.366(c) to reflect the approval. The basis for approval is discussed in the freedom of information summary.

This approval is for use of Type A medicated articles to make combination drug Type C medicated feeds. Nicarbazin is a category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved Form FDA 1900 is required to make a Type C medicated feed from a category II drug. Under 21 U.S.C. 360b(m), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250), medicated feed applications have been replaced by a requirement for feedmill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 141-146 is limited to manufacture in a licensed feedmill.

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.

The agency has determined under 21 CFR 25.33(a)(2) 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 558.78 is amended by adding paragraph (d)(3)(xxi) to read as follows:

§ 558.78 Bacitracin zinc.

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(d) * * *

(3) * * *

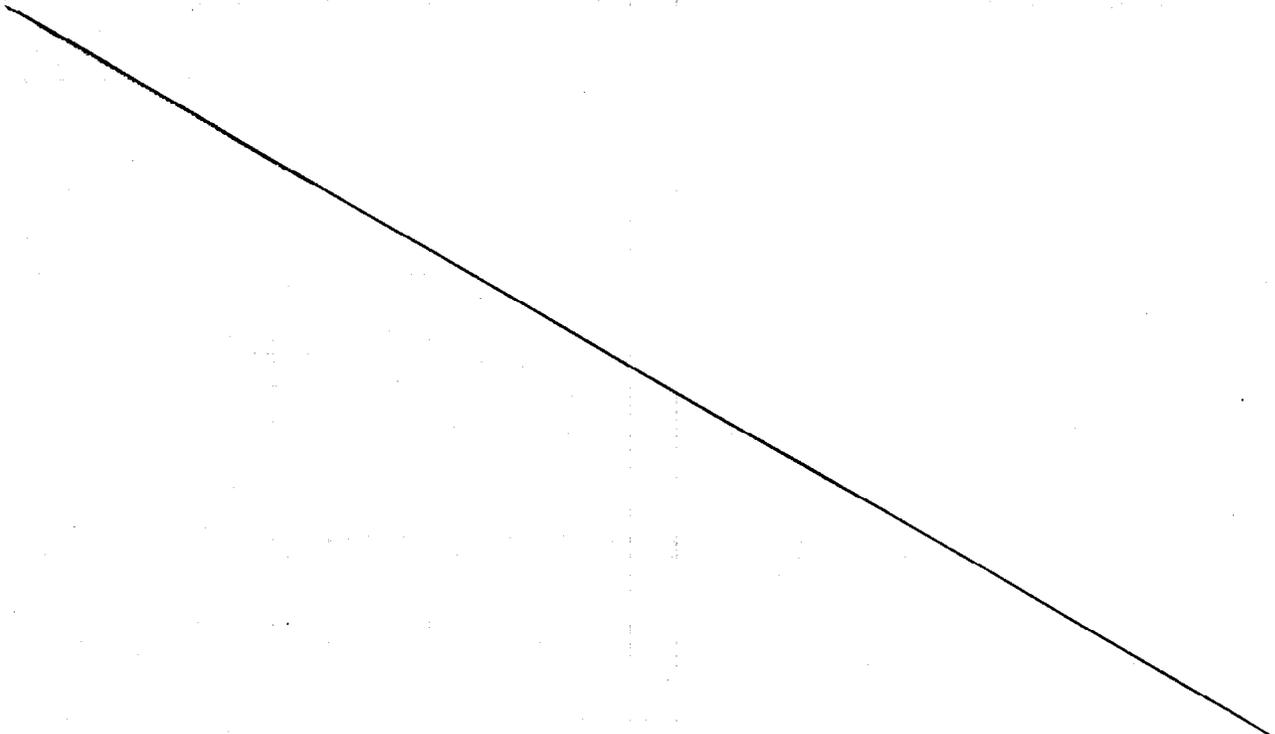
(xxi) Nicarbazin as in § 558.366.

3. Section 558.366 is amended in the table in paragraph (c) under the entry for “113.5 (0.0125 pct)” by alphabetically adding an entry for “Bacitracin zinc 4 to 50” to read as follows:

§ 558.366 Nicarbazin.

* * * * *

(c) * * *



Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* 113.5 (0.0125 pct) *	* Bacitracin zinc 4 to 50. *	* * * * * * * * * *	* * * * * * * * * *	* * * * * * * * * *

Dated: 2/25/00
February 25, 2000

S F Sundlof

Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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