

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

Display Date 5-15-02

Publication Date 5-16-02

Certifier D. Hawkins

**New Animal Drugs for Use in Animal Feeds; Diclazuril**

**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 Schering-Plough Animal Health Corp. The NADA provides for use of approved single-ingredient diclazuril, bacitracin methylene disalicylate, and roxarsone Type A medicated articles to make three-way combination drug Type C medicated feeds for broiler chickens.

**DATES:** This rule 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, e-mail: candres@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, filed NADA 141-190 that provides for use of CLINACOX (0.2 percent diclazuril), BMD (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate), and 3-NITRO (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination drug Type C medicated feeds for broiler chickens. The Type C feeds contain 0.91 g/ton diclazuril, 50 or 100 to 200 g/ton bacitracin methylene disalicylate, and 22.7 to 45.4 g/ton roxarsone and are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis (mivati)*, and *E. maxima*; as an aid in the prevention (at 50 g/ton bacitracin) or control (at 100 to 200 g/ton bacitracin) of necrotic enteritis caused or

complicated by *Clostridium* spp. or other organisms susceptible to bacitracin; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of December 14, 2001, and the regulations are amended in 21 CFR 558.198 to reflect the approval.

The regulations in 21 CFR 558.76 and 558.530 are also being amended to cross-reference approved combinations. The basis of 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 each 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.

§ 558.76 [Amended]

2. Section 558.76 *Bacitracin methylene disalicylate* is amended by redesignating paragraphs (d)(3)(v) to (d)(3)(xvii) as paragraphs (d)(3)(vi) to (d)(3)(xviii); and by adding new paragraph (d)(3)(v) to read “Diclazuril alone and with roxarsone as in § 558.198.”

3. Section 558.198 is amended by redesignating paragraph (b) as paragraph (c); and paragraphs (d)(1)(iii) through (d)(1)(v) as paragraphs (d)(1)(v) through (d)(1)(vii), respectively; by revising paragraph (a), by adding new paragraphs (b) and (d)(1)(iii) and (d)(1)(iv) to read as follows:

§ 558.198 **Diclazuril.**

(a) *Specifications.* Type A medicated article containing 0.2 percent diclazuril.

(b) *Approvals.* See No. 000061 in § 510.600(c) of this chapter.

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(iii) 0.91 (1 ppm).	Bacitracin methylene disalicylate 50 plus roxarsone 22.7 to 45.4	Broiler chickens: As in item (i) of this table; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration throughout growing period. Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone provided by No. 046573 in §510.600(c) of this chapter.	000061
(iv) 0.91 (1 ppm).	Bacitracin methylene disalicylate 100 to 200 plus roxarsone 22.7 to 45.4	Broiler chickens: As in item (i) of this table; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as the sole ration throughout growing period. Start at first clinical signs of disease; vary dosage of bacitracin based on severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 grams per ton (g/ton). Use as sole source of organic arsenic; drug overdose or lack of water may result in leg weakness. Not for use in hens producing eggs for human consumption. Withdraw 5 days before slaughter. Bacitracin methylene disalicylate and roxarsone provided by No. 046573 in §510.600(c) of this chapter.	000061

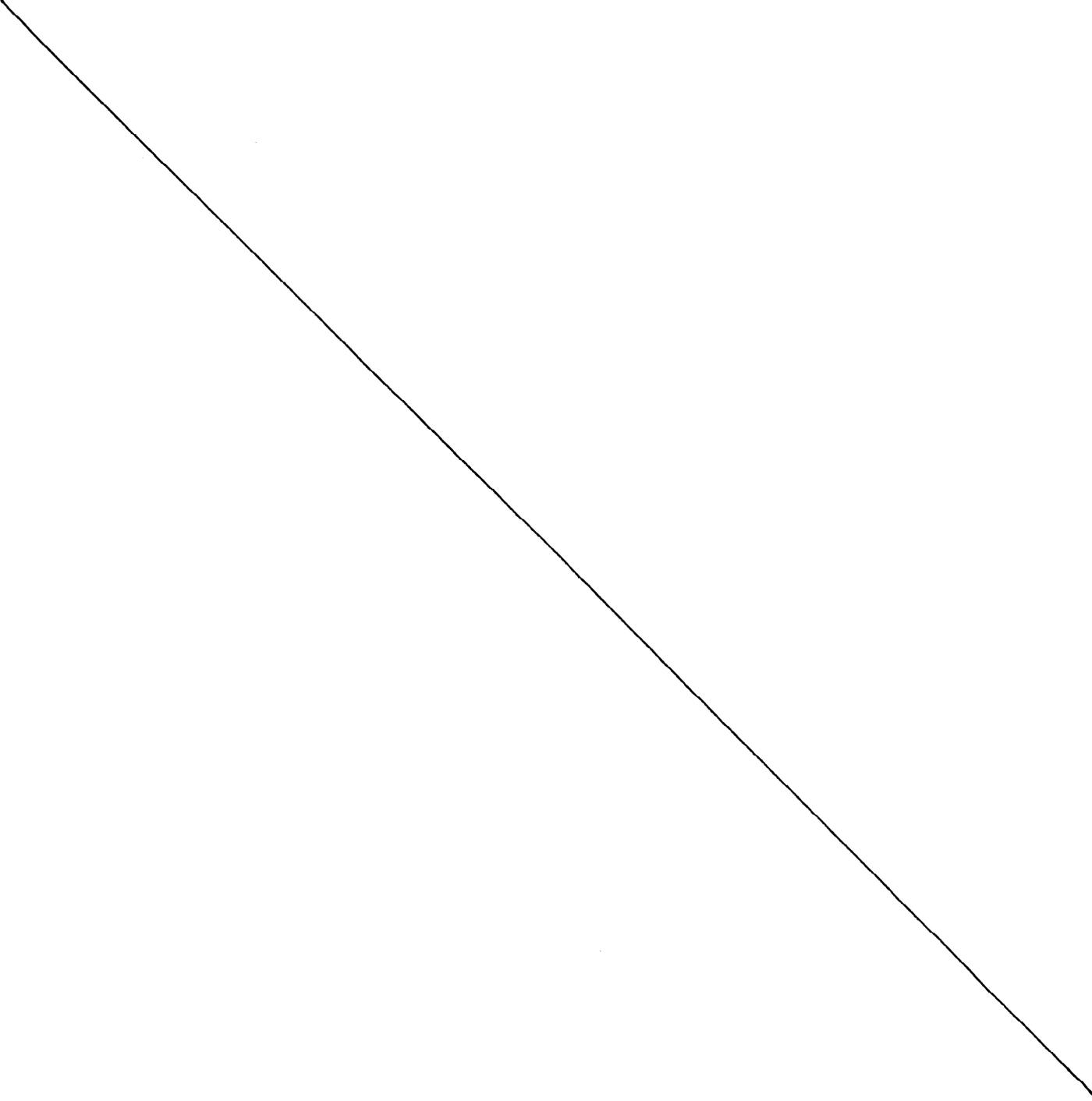
\* \* \* \* \*

**§ 558.530 [Amended]**

4. Section 558.530 *Roxarsone* is amended by revising paragraph (d)(5)(x) to read as follows:

\* \* \* \* \*

(d) \* \* \*



(5) \* \* \*

(x) Diclazuril alone or in combination as in § 558.198.

\* \* \* \* \*

Dated: 3/15/02

March 15, 2002.

LB  
4-26-02



Stephen F. Sundlof,  
Director,  
Center for Veterinary Medicine.

[FR Doc. 02-????? Filed ??-??-02; 8:45 am]

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE  
COPY OF THE ORIGINAL

Dawn P. Hawkins