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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Diclazuril, Bacitracin Methylene Disalicylate, Bambermycins, and Virginiamycin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of three new animal drug applications (NADA's) filed by Schering-Plough Animal Health Corp. The NADA's provide for use of the approved, single-ingredient diclazuril Type A medicated article together with approved, single-ingredient Type A medicated articles for either bacitracin methylene disalicylate (BMD), virginiamycin, or bambermycins to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in 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.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 3182, Union, NJ 07083, filed three NADA's that provide for use of Clinacox™ (0.91 grams per pound (g/lb) diclazuril activity) Type A medicated article together with other approved, single-ingredient Type A medicated articles to make two-way combination Type C medicated broiler chicken feeds used for the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mitis* (*mivati*), and *E. maxima*. Because diclazuril is effective against

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*E. maxima* later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with *E. maxima*. The combination Type C medicated feeds are also used for increased rate of weight gain and for improved feed efficiency.

NADA 141-153 provides for use of Clinacox™ and BMD® (10, 25, 30, 50, 60, or 75 g/lb bacitracin activity as BMD) Type A medicated articles to make combination Type C medicated broiler chicken feed containing 0.91 g/ton diclazuril and 4 to 50 g/ton BMD® and is approved as of January 13, 2000.

NADA 141-158 provides for use of Clinacox™ and Flavomycin® (2, 4, or 10 g/lb of bambarmycins activity) Type A medicated articles to make combination Type C medicated broiler chicken feed containing 0.91 g/ton diclazuril and 1 to 2 g/ton bambarmycins and is approved as of July 3, 2000.

NADA 141-090 provides for use of Clinacox™ and Stafac® (5, 10, 20, 50, or 227 g/lb virginiamycin activity) Type A medicated articles to make combination Type C medicated broiler chicken feed containing 0.91 g/ton diclazuril and 5 or 5 to 15 g/ton virginiamycin and is approved as of January 13, 2000. The combination Type C medicated feed containing 5 g/ton virginiamycin is used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency. The combination Type C medicated feed containing 5 to 15 g/ton virginiamycin is used for prevention of coccidiosis and increased rate of weight gain only.

The regulations are amended in 21 CFR 558.76, §§ 558.95, 558.198 and 558.635 (21 CFR 558.95, 558.198 and 558.635) to reflect these approvals. The basis of approval for each application is discussed in separate freedom of information summaries.

Sections 558.95 and 558.635 are also amended editorially to consolidate the cross-references for approved combinations in paragraph (d) and to list them in alphabetical order.

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 these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither environmental assessments nor environmental impact statements are 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 558.76 is amended by redesignating paragraphs (d)(3)(v) through (d)(3)(xvii) as (d)(3)(vi) through (d)(3)(xviii) and by adding new paragraph (d)(3)(v) to read as follows:

**§ 558.76 Bacitracin methylene disalicylate.**

\* \* \* \* \*

(d) \* \* \*

(3) \* \* \*

(v) Diclazuril as in § 558.198.

\* \* \* \* \*

3. Section 558.95 is amended by revising paragraphs (d)(5)(i) through (d)(5)(iv) to read as follows:

**§ 558.95 Bambermycins.**

\* \* \* \* \*

(d) \* \* \*

(5) Bambermycins may be used in combination with:

(i) Diclazuril as in § 558.198.

(ii) Halofuginone as in § 558.265.

(iii) Narasin alone or with roxarsone as in § 558.363.

(iv) Nicarbazine as in § 558.366.

4. Section 558.198 is amended by revising paragraph (d) to read as follows:

**§ 558.198 Diclazuril.**

\* \* \* \* \*

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

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 part per million (ppm))		Broiler chickens: For the prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. brunetti</i> , <i>E. mitis</i> ( <i>mivati</i> ), and <i>E. maxima</i> . Because diclazuril is effective against <i>E. maxima</i> later in its life cycle, subclinical intestinal lesions may be present for a short time after infection. Diclazuril was shown in studies to reduce lesion scores and improve performance and health of birds challenged with <i>E. maxima</i> .	Feed continuously. Not for use in hens producing eggs for human food.	000061
(ii) 0.91 (1 ppm)	Bacitracin methylene disalicylate 4 to 50	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency.	As in item (i) of this table. Bacitracin methylene disalicylate provided by 046573.	000061
(iii) 0.91 (1 ppm)	Bambermycins 1 to 2	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency.	As in item (i) of this table. Bambermycins provided by 012799.	000061
(iv) 0.91 (1 ppm)	Virginiamycin 5	Broiler chickens: As in item (i) of this table; for increased rate of weight gain and improved feed efficiency.	As in item (i) of this table; Virginiamycin provided by 000069.	000061

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(v) 0.91 (1 ppm)	Virginiamycin 5 to 15	Broiler chickens: As in item (i) of this table; for increased rate of weight gain.	As in item (i) of this table. Virginiamycin provided by 000069.	000061

(2) [Reserved]

5. Section 558.635 is amended by revising paragraphs (d)(4)(i) through (d)(4)(vii) to read as follows:

**§ 558.635 Virginiamycin.**

\* \* \* \* \*

(d) \* \* \*

(4) Virginiamycin may be used in combination with:

(i) Amprolium and ethopabate as in § 558.58.

(ii) Diclazuril as in § 558.198.

(iii) Halofuginone as in § 558.265.

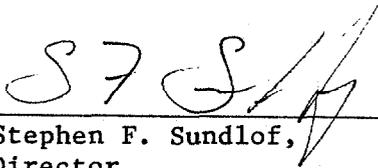
(iv) Lasalocid as in § 558.311.

(v) Monensin alone or with roxarsone as in § 558.355.

(vi) Salinomycin alone or with roxarsone as in § 558.550.

(vii) Semduramicin as in § 558.555.

Dated: 7/26/00  
July 26, 2000



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

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