

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

Display Date 7/17/02

Publication Date 7/18/02

Certifier [Signature]

New Animal Drugs for Use in Animal Feeds; Diclazuril and Bacitracin Methylene Disalicylate

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 and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds for growing turkeys.

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 141-194 that provides for use of CLINACOX (0.2 percent diclazuril) and BMD (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) Type A medicated articles to make two-way combination drug Type C medicated feeds for growing turkeys. The Type C feeds contain 0.91 g/ton diclazuril and 4 to 50 g/ton bacitracin methylene disalicylate, and they are used for the prevention of coccidiosis caused by *Eimeria adenoeides*, *E. gallopavonis*, and *E. meleagritidis*, and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of April 2, 2002, and the

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NADA 141-194

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regulations are amended in 21 CFR 558.198 to reflect the approval. 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.

2. Section 558.198 is amended by ^{adding} revising paragraph (d)(2)(ii) to read as follows:

*Pen JFR
g/p 7/16/02*

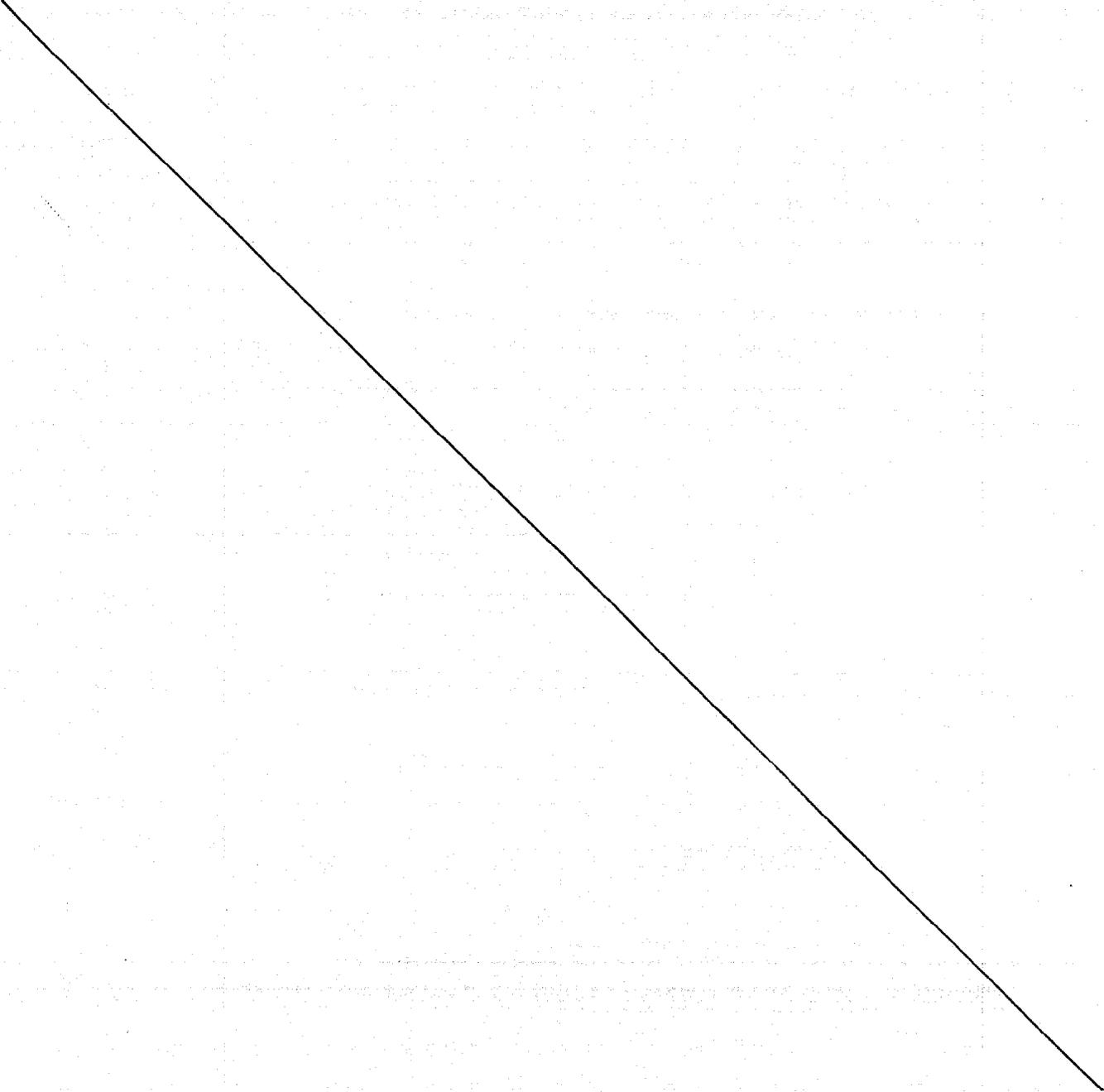
§ 558.198 Diclazuril.

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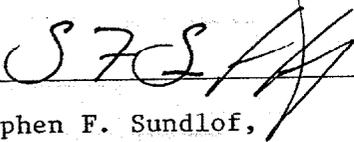
(d) * * *

(2) * * *

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(ii) 0.91 (1 ppm).	Bacitracin methylene disalicylate 4 to 50.	Growing turkeys: As in paragraph (d)(2)(i) of this section; for increased rate of weight gain and improved feed efficiency.	As in paragraph (d)(2)(i) of this section. Bacitracin methylene disalicylate provided by No. 046573 in § 510.600(c) of this chapter.	000061



Dated: 7/8/02
July 8, 2002.



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

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

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