

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Parts 556 and 558

Animal Drugs, Feeds, and Related Products; Diclazuril

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 a new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for the use of a Type A medicated article containing diclazuril for use in manufacturing a Type C medicated feed indicated for the prevention of coccidiosis in broiler chickens.

**EFFECTIVE DATE:** *(Insert date of publication in the Federal Register.)*

**FOR FURTHER INFORMATION CONTACT:** Janis R. Messenheimer, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7578.

**SUPPLEMENTARY INFORMATION:** Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed NADA 140-951, which provides for the use of a Type A medicated article containing 0.2 percent of diclazuril (Clinacox™) for use in manufacturing a Type C medicated feed indicated for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis (mivati)*, and *E. maxima*. Because diclazuril is effective against *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 NADA is approved as of April 21, 1999,

and the regulations are amended in 21 CFR part 558 by adding § 558.198 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, the regulations are amended in 21 CFR part 556 by adding § 556.175 to establish tolerances for diclazuril residues in the edible tissues of chickens and to establish an acceptable daily intake (ADI) for total diclazuril residues. The ADI represents the total amount of drug residue that can safely be consumed by humans every day.

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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity for the use of diclazuril in chicken feed beginning April 21, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been approved in any other application.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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

### *21 CFR Part 556*

Animal drugs, Foods.

### *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 parts 556 and 558 are amended as follows:

## **PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

2. Section 556.175 is added to subpart B to read as follows:

### **§ 556.175 Diclazuril.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of diclazuril is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances*. (1) Chickens: Tolerances are established for residues of parent diclazuril at 0.5 part per million (ppm) in muscle, 3 ppm in liver, and 1 ppm in skin/fat.

(2) [Reserved]

## **PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

4. Section 558.198 is added to subpart B to read as follows:

**§ 558.198 Diclazuril.**

(a) *Approvals.* Type A medicated article: 0.2 percent of diclazuril to 000061 in § 510.600(c) of this chapter.

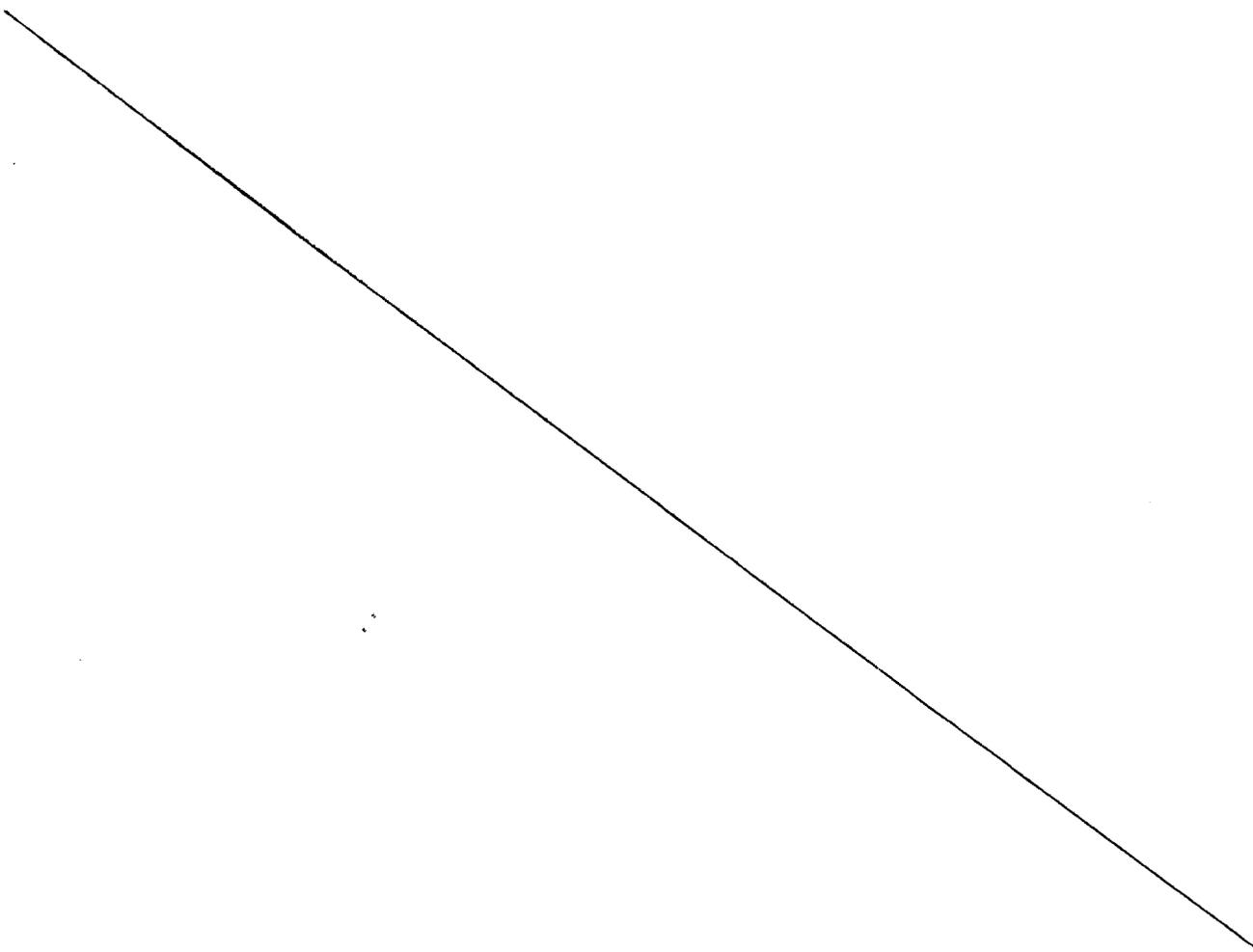
(b) *Related tolerances.* See § 556.175 of this chapter.

(c) [Reserved]

(d) *Conditions of use.* It is used in broiler chickens as follows:

(1) *Amount.* 1 part per million (ppm).

(2) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mitis (mivati)*, and *E. maxima*. Because diclazuril is effective against *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*.



(3) *Limitations.* Feed continuously. Not for use in hens producing eggs for human food.

Dated: 6/4/99  
June 4, 1999

SFS/A

Stephen F. Sundlof  
Director  
Center for Veterinary  
Medicine

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Michael W. Bell