DEPARTMENT OF HEALTH AND HUMAN SERVICES

DMB

Display Date 12-3-01
Publication Date 12-4-01
Certifier SREESE

Food and Drug Administration

21 CFR Parts 556 and 558,

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 supplemental new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The NADA provides for use of the approved diclazuril Type A medicated article to make Type B and Type C medicated feeds used for prevention of coccidiosis in growing turkeys. Also, tolerances for diclazuril residues in turkey liver, muscle, and skin with adherent fat are being established.

DATES: This rule is effective *[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., P.O. Box 3182, Union, NJ 07083, fifed a supplement to NADA 140-951 that provides for use of CLINACOX '(0.2 percent diclazuril) Type A medicated article to make Type B and Type C medicated turkey feeds used for the prevention of coccidiosis caused by *Eimeria adenoeides, E. gallopavonis*, and *E. meleagrimitis*. The NADA is approved as of September 21, 2001, and the regulations are being amended in §§ 556.175 and 558.198 (21 CFR 556.175 and 558.198) to reflect the approval. In addition, § 556.175 is being redesignated as $556.185 to place it in alphabetical

NFR1

order in 21 CFR part 556. 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning September 21, 2001, because the application contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivaleuce or residue studies) required for approval of the application and conducted or sponsored by the applicant.

The agency has carefully considered the potential environmental impact of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. FDA'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, Food.

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.

5556.175 [Redesignated'as § 556.1851

2. Section 556.175 is redesignated as § 556.185 and is amended by revising paragraph (b)(l) and by adding paragraph (b)(2) to read as follows:

§ 556.185 Diclazuril.

* * * * *

(b) *Tolerances-(l) Chickens-(i) Liver.* The tolerance for parent diclazuril (the marker residue) is 3 parts per million (ppm).

(ii) Muscle. The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat.* The tolerance for parent diclazuril (the marker residue) is 1 ppm.

(2) Turkeys--(i) Liver. The tolerance for parent diclazuril (the marker residue) is 3 ppm.

(ii) *Muscle.* The tolerance for parent diclazuril (the marker residue) is 0.5 ppm.

(iii) *Skin/fat.* The tolerance for parent diclazuril (the marker residue) is 1 ppm.

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 amended in paragraph (b) by removing "556.175" and by adding in its place "556.185"; and in paragraph (d)(l) by Adding a heading and by revising the introductory text, and by adding paragraph (d)(2) to read as follows:

§ 558.198 Diclazuril.

* * * * *

(d) *Conditions of use*—(1) *Chickens.* For chickens it is used as follows:

* * * * *

(2) Turkeys. For turkeys it is used as follows:

Diclazuril grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 0.91 (1 ppm)	.....	Growing turkeys: For the prevention of coccidiosis caused by *E. adenoeides, E. gallopavonis* and *E. meleagrimitis*..	Feed continuously as the sole ration. Do not feed to breeding turkeys. Not for use in hens producing eggs for human consumption..	000061
(ii) [Reserved]	.....	.....	.....	

Dated: 11/9/01

November 9, 2001.

cvo15

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

[FR Doc. 01–????? Filed ??-??-Ol; 8:45 am)

BILLING CODE 4160-01-S

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL