

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

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Display Date 11-16-04
Publication Date 11-17-04
Certifier D. Hawkins

New Animal Drugs for Use in Animal Feeds; Decoquinatate; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its animal drug regulations to more accurately describe the approved feeding instructions for decoquinatate Type C medicated feeds for cattle and calves, including nonruminating veal calves, and for young sheep and young goats. This action is being made to improve the accuracy of the regulations.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV 6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: george.haibel@fda.gov.

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2004, edition of the Code of Federal Regulations part 500 to 599 (21 CFR 500 to 599) does not reflect the feeding instructions for decoquinatate in Type C medicated feeds for cattle and calves, including nonruminating veal calves, and for young sheep and young goats approved under NADA 39-417 (67 FR 72370, December 5, 2002). At this time, FDA is amending the regulations to correct this error in § 558.195. An inaccurate and unnecessary description of a Type B medicated

feed is also being removed. These changes are being made to improve the accuracy of the regulations.

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 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 558.195 is amended by revising paragraphs (e)(2)(i), (e)(2)(ii), and (e)(3)(ii) in the table to read as follows:

§ 558.195 Decoquinat.

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(e) * * *

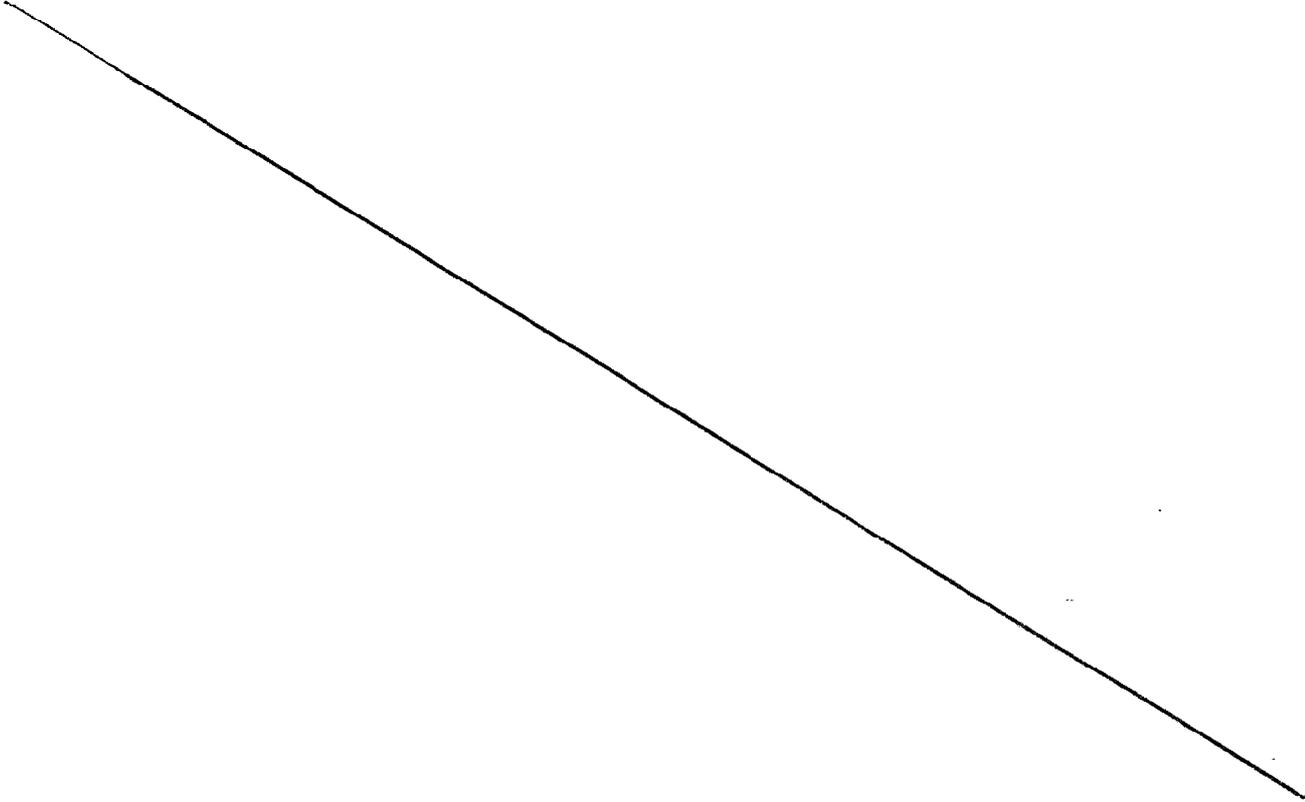
(2) * * *

Decoquinat in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 12.9 to 90.8		Cattle (including ruminating and nonruminating calves and veal calves): For prevention of coccidiosis caused by <i>Eimeria bovis</i> and <i>E. zuernii</i>	Feed Type C feed or milk replacer to provide 22.7 milligrams (mg) per 100 pounds (lb) of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section	046573

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(ii) 90.9 to 535.7		Cattle (including ruminating and nonruminating calves and veal calves): As in paragraph (e)(2)(i) of this section	Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lb of body weight (0.5 mg/kg) per day. Feed at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to cows producing milk for food. See paragraph (d)(3) of this section	046573
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(3) * * *

Decoquinatate in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
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(ii) 90.9 to 535.7		<p>1. Young sheep: As in item 1 of paragraph (e)(3)(i) of this section</p> <p>2. Young goats: As in item 2 of paragraph (e)(3)(i) of this section</p>	<p>Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to sheep producing milk for food</p> <p>Feed Type C medicated feed supplements as a top dress or mix into the daily ration to provide 22.7 mg per 100 lbs of body weight (0.5 mg per kg) per day; feed for at least 28 days during periods of exposure to coccidiosis or when it is likely to be a hazard. Do not feed to goats producing milk for food</p>	046573
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Dated: 11/4/04
November 4, 2004.



Stephen F. Sundlof,
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[FR Doc. 04-????? Filed ??-??-04; 8:45 am]

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