Rules and Regulations

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

Federal Old-Age, Survivors, and Disability Insurance (1950-)

CFR Correction

In Title 20 of the Code of Federal Regulations, parts 400 to 499, revised as of April 1, 1998, § 404.2(b)(1) is corrected to read as follows:

§ 404.2 General definitions and use of terms.

* * * * *

(b) * * * (1) *Commissioner* means the Commissioner of Social Security.

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[FR Doc. 99–55508 Filed 3–1–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 556

Oral Dosage Form New Animal Drugs; Decoquinate

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 Alpharma Inc. The NADA provides for adding a dry powder containing decoquinate to whole milk to be fed to calves for prevention of coccidiosis. Also, the regulations are amended to codify an acceptable daily intake (ADI) for decoquinate residues.

EFFECTIVE DATE: March 2, 1999.)

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–060 that provides for adding an 0.8 percent decoquinate medicated powder to whole milk to be fed to ruminating and nonruminating calves including veal calves for prevention of coccidiosis caused by *Eimeria bovis* and *E. zurni*. The NADA is approved as of January 14, 1999, and the regulations are amended by adding 21 CFR 520.534 to reflect the approval.

In addition, FDA is codifying the ADI for decoquinate previously established in Alpharma Inc.'s NADA 39–417 in 21 CFR 556.170.

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.

The agency has determined under 21 CFR 25.33(a)(1) 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.

List of Subjects

21 CFR Part 520

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 520 and 556 are amended as follows:

PART 520— ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.534 is added to read as follows:

§ 520.534 Decoquinate.

(a) *Specifications*. The drug is a powder containing 0.8 percent decoquinate.

(b) *Sponsor*. See No. 046573 in § 510.600(c) of this chapter.

(c) *Related tolerances*. See § 556.170 of this chapter.

(d) *Conditions of use. Replacement calves*—(1) *Amount*. Feed 22.7 milligrams per 100 pounds of body weight (0.5 milligram per kilogram) per day.

(2) *Indications for use*. For the prevention of coccidiosis in ruminating and nonruminating calves, including veal calves, caused by *Eimeria bovis* and *E. zuernii*.

(3) *Limitations*. Feed in whole milk at the rate of 22.7 milligrams per 100 pounds body weight daily (0.5 milligram per kilogram) for at least 28 days.

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

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

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

4. Section 556.170 is revised to read as follows:

§ 556.170 Decoquinate.

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of decoquinate is 75 micrograms per kilogram of body weight per day.

(b) *Tolerances*. Tolerances are established for residues of decoquinate in the uncooked, edible tissues of chickens, cattle, and goats as follows:

(1) 1 part per million (ppm) in skeletal muscle.

(2) 2 ppm in other tissues.

Dated: February 19, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–5031 Filed 3–1–99; 8:45 am]

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