

the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 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 supplemental approval qualifies for 3 years of marketing exclusivity for the new indications beginning August 16, 1995, because new clinical or field investigations (other than bioequivalence or residue studies) conducted by the sponsor were required for the approval.

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.

List of Subjects in 21 CFR Part 520

Animal drugs.

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 520 is 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.1445 [Amended]

2. Section 520.1445 *Milbemycin oxime tablets* is amended in paragraph (c)(2) by adding the phrase "and in puppies 4 weeks of age or greater and 2 pounds of body weight or greater." at the end of the paragraph and in paragraph (c)(3) by adding the sentence "Do not use in puppies less than 4 weeks of age and less than 2 pounds in body weight." at the beginning of the paragraph.

Dated: September 15, 1995.

Robert C. Livingston,

*Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.*
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Food and Drug Administration

21 CFR Parts 520 and 556

Animal Drugs, Feeds, and Related Products; Sarafloxacin Hydrochloride

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 Abbott Laboratories. The NADA provides for use of sarafloxacin hydrochloride in turkey and broiler chicken drinking water for control of mortality associated with *Escherichia coli* organisms susceptible to sarafloxacin.

EFFECTIVE DATE: September 28, 1995.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1644.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, 1401 Sheridan Rd., North Chicago, IL 60064-4000, filed NADA 141-017, which provides for use of sarafloxacin hydrochloride (SaraFlox® WSP) water soluble powder to make turkey and broiler chicken medicated drinking water used for control of mortality associated with *E. coli* organisms susceptible to sarafloxacin.

The NADA is approved as of August 18, 1995, and the regulations are amended by adding new § 520.2095 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, part 556 (21 CFR part 556) is amended by adding new § 556.594 to reflect that a tolerance for residues of sarafloxacin in edible turkey and broiler chicken tissues is not required. At zero withdrawal, the total residue of sarafloxacin HC1 in the target tissue (liver) is less than half the safe concentration (5.25 ppm). The marker compound, parent sarafloxacin HC1, represents 20 to 80 percent of the total residue in liver of turkeys and 60 to 80 percent of the total residue in liver of chickens, depending upon the extraction procedure.

In accordance with the freedom of information provisions of part 20 (21

CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, 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 beginning August 18, 1995, because no active ingredient (including any ester or salt thereof) has been previously approved in any other application filed under section 512(b)(1) of the act.

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.

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 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. New § 520.2095 is added to read as follows:

§ 520.2095 Sarafloxacin soluble powder.

(a) *Specifications.* Each 145 grams (5.1 ounces) pouch contains sarafloxacin hydrochloride equivalent to 14.5 grams of sarafloxacin base.

(b) *Sponsor.* See No. 000074 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.594 of this chapter.