

File No.	Type of filing	Retention period
124-11 124-20 124-7, 124-7a .....	Subject files—Drafts, comments and correspondence concerning proposed legislation submitted by the Senate and the House to the Commission for comment.	30 years.
124-7b .....	Drafts of bills not yet reported in Congress that are submitted to the Commission for comment.	30 years.
132-3 .....	General Correspondence—Active companies. Inquiries and complaints concerning companies registered under the various Acts administered by the Commission.	10 years.
132-3 .....	General Correspondence—Inactive companies (no longer required to file reports with the Commission). Inquiries and complaints concerning companies registered under the various Acts administered by the Commission.	6 years.
132-3 .....	General Correspondence—Miscellaneous. Requests for interpretation of rules and regulations under the Acts administered by the Commission.	6 years.
140- .....	Drafts, internal memoranda, correspondence concerning rules and regulations under each of the Acts administered by the Commission.	30 years.
206-, 207- to 215-, 917- .....	Reorganization proceedings under Chapters IX, X, XI of the Bankruptcy Act in which the Commission participates.	30 years.
265- .....	Advisory Committees established by the Commission (correspondence, questionnaires, reports).	30 years.
Confidential treatment materials ....	Periodic reports and other materials containing contracts, commercial and financial information, disclosure of which would impair the value thereof, submitted under confidential cover.	10 years.
CHR .....	SEC Chairman's Subject Case Files .....	20 years.
CHR .....	SEC Chairman's Chronological Files for Period 1972 to Present .....	Chairman's tenure in office plus 3 years.
CHR .....	SEC Chairman's General Subject File .....	Chairman's tenure in office plus 3 years.
COMM .....	SEC Commissioners' Files (excluding Chairman), 1934 to Present .....	Commissioner's tenure in office plus 1 year.
ENF .....	Investigative Case Files—Closed .....	Until closed plus 25 years.
ENF .....	Investigative Case Files—Inactive .....	Until inactive plus 25 years.
LIT .....	Litigation files: 1. Briefs .....	25 years.
	2. File contents other than briefs .....	10 years.
S7 .....	Issuance, amendment or rescission of rules under the various Acts—public comments and views, transcript of hearings, correspondence.	30 years (permanent).
XX .....	Reports of internal inquiries: 1. Supporting documentation .....	Until date of final action plus 5 years, if no report is issued, or until date of final report plus 5 years.
	2. Final reports .....	5 years.

By the Commission.  
 Dated: September 22, 1995.  
 Margaret H. McFarland,  
*Deputy Secretary.*  
 [FR Doc. 95-24032 Filed 9-27-95; 8:45 am]  
**BILLING CODE 8010-10-M**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**  
**Food and Drug Administration**  
**21 CFR Part 520**  
**Oral Dosage Form New Animal Drugs; Milbemycin Oxime**  
**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 Ciba-Geigy Animal Health, Ciba-Geigy Corp. The supplemental NADA provides for the use of milbemycin oxime tablets in puppies 4 weeks of age or greater and 2 pounds (lb) of body weight or greater for the prevention of heartworm disease, control of adult hookworm infections, and removal and control of adult roundworm and whipworm infections.  
**EFFECTIVE DATE:** September 28, 1995.  
**FOR FURTHER INFORMATION CONTACT:** Marcia K. Larkins, Center for Veterinary Medicine (HFV-112), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-0614.  
**SUPPLEMENTARY INFORMATION:** Ciba-Geigy Animal Health, Ciba-Geigy Corp.,

P.O. Box 18300, Greensboro, NC 27419-8300, filed a supplement to NADA 140-915 for INTERCEPTOR® (milbemycin oxime) tablets. The NADA provides for veterinary prescription use of 2.3-, 5.75-, 11.5-, and 23.0-milligrams INTERCEPTOR® tablets for use as an anthelmintic in dogs in the prevention of heartworm disease caused by *Dirofilaria immitis*, control of adult *Ancylostoma caninum* (hookworm), removal and control of adult *Toxocara canis* (roundworm), and *Trichuris vulpis* (whipworm) infections in dogs. The supplement provides for use of the product to treat puppies 4 weeks of age or greater and 2 lb of body weight or greater for the same infections.  
 The supplemental NADA 140-915 is approved as of August 16, 1995, and the regulations are amended by revising 21 CFR 520.1445(c)(2) and (c)(3) to reflect

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.*  
[FR Doc. 95-24160 Filed 9-27-95; 8:45 am]

BILLING CODE 4160-01-F

## **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.