Also, with the withdrawal of approval of NADA 46–147, Babineaux's Veterinary Products is no longer the sponsor of any approved NADA's. Therefore, 21 CFR 510.600(c)(1) and (2) are amended to remove entries for this firm.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 520

Animal drugs.

21 CFR Part 522

Animal drugs.

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 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in paragraph (c)(1) by removing the entry for ''Babineaux's Veterinary Products, Inc.'' and in paragraph (c)(2) by removing the entry for ''021188''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 520.622b [Amended]

4. Section 520.622b *Diethylcarbamazine citrate syrup* is amended in paragraph (a)(2) by removing the phrase ''Nos. 021188 and'' and adding in its place ''No.''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

5. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1680 [Amended]

6. Section 522.1680 *Oxytocin injection* is amended in paragraph (b) by removing the number ''000402''.

§ 522.1720 [Amended]

7. Section 522.1720 *Phenylbutazone injection* is amended in paragraph (b)(2) by removing the number ''000402''.

Dated: July 17, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19066 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Enrofloxacin Tablets

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 Bayer Corp., Agriculture Division, Animal Health. The supplemental NADA provides for revised conditions for use (dose, indications, and limitations) of enrofloxacin tablets in dogs and cats for the management of diseases associated with bacteria susceptible to enrofloxacin.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Division, Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140–441 Baytril® Tablets (5.7, 22.7, or 68.0 milligrams (mg) enrofloxacin). The supplemental NADA provides for revised conditions for use of enrofloxacin in dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin by administering the tablets orally at a rate of 5 to 20 mg per kilogram (2.27 to 9.07 mg/pounds) of body weight as a single daily dose or divided and given in 2 equal daily doses at 12 hour intervals for at least 2 to 3 days beyond cessation of clinical signs, to a maximum of 30 days. The supplemental NADA is approved as of June 19, 1997, and the regulations are amended in § 520.812 (21 CFR 520.812) by redesignating paragraph (c) as paragraph (d) and by reserving new paragraph (c) to provide for more uniform regulations and future expansion. Newly redesignated § 520.812(d) is revised to reflect the approval. The basis for 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 this application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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).

2. Section 520.812 is amended by redesignating existing paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraph (d) to read as follows:

§ 520.812 Enrofloxacin tablets.

* * * * *

(c) [Reserved]

(d) *Conditions of use.* (1) *Amount.* 5 to 20 milligrams per kilogram (2.27 to 9.07 milligrams per pound) of body weight.

(2) *Indications for use.* Dogs and cats for management of diseases associated with bacteria susceptible to enrofloxacin.

(3) *Limitations.* Administer orally as a single dose or divided into 2 equal doses at 12 hour intervals, daily. Administer for at least 2 to 3 days beyond cessation of clinical symptoms, for a maximum of 30 days. Safety in breeding or pregnant cats has not been established. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: July 9, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19125 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Enrofloxacin Solution

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 Bayer Corp., Agriculture Div., Animal Health. The supplemental NADA provides for revised indications for use of enrofloxacin injectable solution in dogs for the management of diseases associated with bacteria susceptible to enrofloxacin.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Linda M. Wilmot, Center for Veterinary Medicine (HFV–114), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–0614.

SUPPLEMENTARY INFORMATION: Bayer Corp., Agriculture Div., Animal Health, P.O. Box 390, Shawnee Mission, KS 66201, filed supplemental NADA 140–913 Baytril Injectable Solution (22.7 milligrams enrofloxacin per milliliter) to provide for revised indications for use of enrofloxacin for dogs for management of diseases associated with bacteria susceptible to enrofloxacin. The supplemental NADA is approved as of June 19, 1997. The basis of approval is discussed in the freedom of information summary.

The regulations are amended in § 522.812 (21 CFR 522.812) by redesignating paragraph (c) as paragraph (d) and by reserving paragraph (c) to provide for more uniform regulations and future expansion. Newly redesignated § 522.812(d)(2) is revised to reflect the approval.

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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.812 is amended by redesignating existing paragraph (c) as paragraph (d), by reserving paragraph (c), and by revising newly redesignated paragraph (d)(2) to read as follows:

§ 522.812 Enrofloxacin solution.

* * * * *

(c) [Reserved]

(d) * * *

(2) *Indications for use.* Dogs for management of diseases associated with bacteria susceptible to enrofloxacin.

* * * * *

Dated: July 9, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–19126 Filed 7–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin

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 Merck Research Laboratories, Division of Merck & Co., Inc. The supplemental NADA provides for topical use of ivermectin for control of infections of gastrointestinal roundworms for 14 days following use on cattle.

EFFECTIVE DATE: July 21, 1997.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, filed supplemental NADA 140–841 that provides for the use of Ivomec® pour-on (5 milligrams of ivermectin per milliliter) for cattle to control infections of gastrointestinal roundworms *Ostertagia ostertagi*, *Oesophagostomum radiatum*, *Haemonchus placei*, *Trichostrongylus axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment. The supplemental NADA is approved as of June 5, 1997, and the regulations are amended in 21 CFR 524.1193(d)(2) 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 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, 12420 Parklawn Dr., rm. 1–23, 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 for food-producing animals qualifies for 3 years of marketing exclusivity beginning June 5, 1997, because the supplement