authority delegated to the Commissioner of Food and Drug and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 184 is amended as follows:

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

1. The authority citation for 21 CFR part 184 continues to read as follows:

Authority: Secs. 201, 402, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 342, 348, 371).

2. New § 184.1985 is added to read as follows:

§ 184.1985 Aminopeptidase enzyme preparation derived from lactococcus lactis.

(a) Aminopeptidase enzyme preparation is derived from the nonpathogenic and nontoxicogenic bacterium *Lactococcus lactis* (previously named *Streptococcus lactis*). The preparation contains the enzyme aminopeptidase (CAS Reg. No. 9031–94–1; EC 3.4.11.1) and other peptidases that hydrolyze milk proteins. The preparation is produced by pure culture fermentation.

(b) The ingredient meets the specifications for enzyme preparations in the Food Chemicals Codex, 3d ed. (1981), pp. 107–110, which are incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Division of Petition Control (HFS–215), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 1110 Vermont Ave. NW., suite 1200, Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) In accordance with § 184.1(b)(1), the ingredient is used in food with no limitations other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as an enzyme, as defined in § 170.3(o)(9) of this chapter, as an optional ingredient for flavor development in the manufacture of cheddar cheese, in accordance with § 133.113 of this chapter, and in the preparation of protein hydrolysates.

(2) The ingredient is used at levels not to exceed current good manufacturing practice.

Dated: September 29, 1995.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 95–26054 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 510

New Animal Drugs; Change of Sponsor Name

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor name from Miles, Inc., Agriculture Division, Animal Health Products to Bayer Corp., Agriculture Division, Animal Health.

EFFECTIVE DATE: October 20, 1995.

FOR FURTHER INFORMATION CONTACT: Benjamin A. Puyot, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1646.

SUPPLEMENTARY INFORMATION: Miles, Inc., Agriculture Division, Animal Health Products, P.O. Box 390, Shawnee Mission, KS 66201–0390, has informed FDA of a change of sponsor name to Bayer Corp., Agriculture Division, Animal Health. Accordingly, FDA is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor name.

List of Subjects in 21 CFR Part 510

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

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 510 is 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 the table in paragraph (c)(1) by removing the entry for ''Miles, Inc., Agriculture Division, Animal Health Products,'' and by alphabetically adding a new entry for ''Bayer Corp., Agriculture Division, Animal Health,'' and in the table in paragraph (c)(2) in the entry for ''000859'' by removing the sponsor name ''Miles, Inc., Agriculture Division, Animal Health Products'' and adding in its place ''Bayer Corp., Agriculture Division, Animal Health.''

Dated: October 5, 1995.

Robert C. Livingston,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 95–25958 Filed 10–19–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 two supplemental new animal drug applications (NADA's) filed by Hoffmann-La Roche, Inc. One supplemental NADA provides for the addition of certain lasalocid-containing Type A medicated articles to dry, powdered milk replacer before reconstitution. The reconstituted Type C medicated feed is used to control coccidiosis in nonveal calves. Additionally, FDA is amending the regulations to reflect approval of another supplemental NADA which modifies the lasalocid feeding directions for control of coccidiosis in cattle.

EFFECTIVE DATE: October 20, 1995.

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: Hoffmann-La Roche, Inc., Nutley, NJ 07110, is the sponsor of NADA 96–298, which currently provides for the use of several concentrations of lasalocid sodium-containing Type A medicated articles in making Type C medicated cattle feeds (68 to 113 grams of activity per ton) for the control of coccidiosis caused by *Eimeria bovis* and *E. zuernii*. The firm has filed a supplemental NADA that expands this use of the drug to nonveal calves using milk replacer powder.

Additionally, FDA concurred with another supplemental NADA which was filed to modify the feeding directions for lasalocid medicated feed when used to