

Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: FS Services, Inc., 1701 Towanda Ave., Bloomington, IL 61701, has changed the firm name to Growmark, Inc. On the firm's behalf, Elanco Products Co. advised the agency of the change of sponsor name. The Bureau of Veterinary Medicine is amending the regulations in 21 CFR 510.600(c) to reflect the change.

This action, the change of sponsor of an NADA, does not involve changes in manufacturing facilities, equipment, procedures, or personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 84367; December 23, 1977), approval of this action does not require reevaluation of the safety and effectiveness data in the parent application.

The agency has determined pursuant to 21 CFR 25.24(d)(1) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), § 510.600 is amended in paragraph (c)(1) by deleting the entry for "FS Services, Inc.," and by adding a new sponsor entry alphabetically for "Growmark, Inc.," and in paragraph (c)(2) in the entry for "020275" by deleting the sponsor name "FS Services, Inc.," and inserting in its place the name "Growmark, Inc.," to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address

Drug
labeler
code

Growmark, Inc., 1701 Towanda Ave., Bloomington, IL 61701.

020275

(2) * * *

Drug
labeler
code

Firm name and address

020275 Growmark, Inc., 1701 Towanda Ave., Bloomington, IL 61701.

Effective date: February 3, 1981.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360(i)))

Dated: January 28, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

(FR Doc. 81-3952 Filed 2-3-81; 8:45 am)

BILLING CODE 4110-03-M

21 CFR Parts 510, 520, and 522

Animal Drugs, Feeds, and Related Products; Wellcome Animal Health Division; Change of Sponsor Name

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect the change of sponsor names for several new animal drug applications (NADA's) from Wellcome Veterinary Division and Jensen-Salsbery Laboratories (two Burroughs Wellcome divisions) to Wellcome Animal Health Division. Supplemental NADA's filed by Burroughs Wellcome Co. provide for the changes.

EFFECTIVE DATE: February 3, 1981.

FOR FURTHER INFORMATION CONTACT:

Sandra K. Woods, Bureau of Veterinary Medicine (HFV-114), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3420.

SUPPLEMENTARY INFORMATION:

Burroughs Wellcome Co. informed the agency that the firm has combined its two veterinary divisions, Wellcome Veterinary Division and Jensen-Salsbery Laboratories, into a single unit to be known as the Wellcome Animal Health Division. The firm submitted supplemental applications for those NADA's affected. The regulations are amended to reflect the change of sponsor name.

This intracorporate transfer of NADA's does not involve changes in facilities, equipment, procedures, or production personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 84367; December 23, 1977), this is a Category I change; therefore, this action does not require a reevaluation of the safety and effectiveness data in the parent applications.

The agency has determined pursuant to 21 CFR 25.24(d)(1) (44 FR 71742; December 11, 1979) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510, 520, and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. In Part 510, § 510.600 is amended in paragraph (c)(1) by removing the entries for "Burroughs Wellcome Co.," and "Jensen-Salsbery Laboratories" and alphabetically adding a new sponsor and in paragraph (c)(2) by removing the entry for "017220" and revising the entry for "000081" to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

(c) * * *

(1) * * *

Firm name and address

Drug
labeler
code

Wellcome Animal Health Division, Burroughs Wellcome Co., Kansas City, MO 64108.

000081

(2) * * *

Drug
labeler
code

Firm name and address

000081 Wellcome Animal Health Division, Burroughs Wellcome Co., Kansas City, MO 64108.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

2. Part 520 is amended:

§ 520.82a [Amended]

a. In § 520.82a *Aminopropazine fumarate tablets*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 520.82b [Amended]

b. In § 520.82b *Aminopropazine fumarate, neomycin sulfate tablets*, in

paragraph (b) by removing "017220" and inserting in its place "000081".

§ 520.784 [Amended]

c. In § 520.784 *Doxylamine succinate tablets*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 520.863 [Amended]

d. In § 520.863 *Ethylisobutrazine hydrochloride tablets*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 520.1720a [Amended]

e. In § 520.1720a *Phenylbutazone tablets and boluses*, in paragraph (b)(1) by removing "017220" and inserting in its place "000081".

§ 520.1720b [Amended]

f. In § 520.1720b *Phenylbutazone granules*, in paragraph (b) by removing "017220" and inserting in its place "000081".

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

3. Part 522 is amended:

§ 522.82 [Amended]

a. In § 522.82 *Aminopropazine fumarate sterile solution injection*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 522.784 [Amended]

b. In § 522.784 *Doxylamine succinate injection*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 522.863 [Amended]

c. In § 522.863 *Ethylisobutrazine hydrochloride injection*, in paragraph (b) by removing "017220" and inserting in its place "000081".

§ 522.1720 [Amended]

d. In § 522.1720 *Phenylbutazone injection*, in paragraph (b)(1) by removing "017220" and inserting in its place "000081".

Effective date. February 3, 1981.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 27, 1981.

Robert A. Baldwin,

Associate Director for Scientific Evaluation.

[FR Doc. 81-3930 Filed 2-3-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Parts 510 and 558

New Animal Drugs and New Animal Drugs for Use in Animal Feeds; Tylosin

Correction

In FR Doc. 80-36872, appearing at page 79027 in the issue of Friday, November 28, 1980, the following changes should be made:

(1) On page 79027, the effective date, "November 29, 1980" should be changed to read "November 28, 1980"

(2) On page 79028, second column, under "§ 558.625 Tylosin", paragraph (b)(73), "03598" should be changed to read "035098"

BILLING CODE 1505-01-M

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs Not Subject to Certification; Praziquantel Injectable Solution

AGENCY: Food and Drug Administration.
ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) amends the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by Bayvet Division, Cutter Laboratories, Inc., providing for safe and effective subcutaneous or intramuscular use of a canine anthelmintic.

EFFECTIVE DATE: February 3, 1981.

FOR FURTHER INFORMATION CONTACT: Bob C. Griffith, Bureau of Veterinary Medicine (HFV-112), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

SUPPLEMENTARY INFORMATION: Bayvet Division, Cutter Laboratories, Inc., P.O. Box 390, Shawnee Mission, KS 66201, filed an NADA (111-607) providing for safe and effective use of praziquantel injectable solution for treating dogs for *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus* infections. Based on the data and information submitted, the NADA is approved and the regulations amended to reflect the approval.

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

(formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Director, Bureau of Veterinary Medicine, has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Director's finding of no significant impact and the evidence supporting this finding, contained in a statement of exemption (pursuant to 21 CFR 25.1(f)(1)(ii)(a) and (e)(1) and (2)) may be seen in the Dockets Management Branch, address above.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended by adding new § 522.1870, to read as follows:

§ 522.1870 Praziquantel injectable solution.

(a) *Specification.* Each milliliter contains 56.8 milligrams of praziquantel.
(b) *Sponsor.* See 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use—(1) Amount.* For dogs 5 pounds and under, 0.3 milliliter (17.0 milligrams); for 6 to 10 pounds, 0.5 milliliter (28.4 milligrams); for 11 to 25 pounds, 1.0 milliliter (56.8 milligrams); if over 25 Pounds, 0.2 milliliter (11.4 milligrams) per 5 pounds body weight to a maximum of 3 milliliters (170.4 milligrams).

(2) *Indications for use.* For removal of canine cestodes *Dipylidium caninum*, *Taenia pisiformis*, and *Echinococcus granulosus*.

(3) *Limitations.* For subcutaneous or intramuscular use; not intended for use in puppies less than 4 weeks of age; Federal law restricts the drug to use by or on the order of a licensed veterinarian.

Effective date. This amendment is effective February 3, 1981.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 23, 1981.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 81-3935 Filed 2-3-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin and Sulfamethazine

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed for Ag-Mark, Inc., providing for safe and effective use of a premix containing 10 grams-per-pound each of tylosin and sulfamethazine for making complete swine feeds.

EFFECTIVE DATE: February 3, 1981.

FOR FURTHER INFORMATION CONTACT:

Jack C. Taylor, Bureau of Veterinary Medicine (HFV-136), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-5247.

SUPPLEMENTARY INFORMATION: Ag-Mark, Inc., P.O. Box 127, East Ave., Teachey, NC 28464, is the sponsor of NADA 124-391 submitted on its behalf by Elanco Products Co. The NADA provides for use of a premix containing 10 grams-per-pound each of tylosin (as tylosin phosphate) and sulfamethazine for making complete swine feeds used to increase rate of weight gain and to improve feed efficiency.

Approval of this application is based on safety and effectiveness data contained in Elanco Products Co.'s approved NADA 41-275. Use of this data in NADA 41-275 to support this application has been authorized by Elanco. This approval does not change the approved use of the drug.

Consequently, approval of this NADA poses no increased human risk from exposure to residues of the animal drug, nor does it change the conditions of the drug's safe use in the target animal species. Accordingly, under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), approval of this NADA has been treated as would approval of a Category II supplemental NADA and does not require reevaluation of the safety and effectiveness data in NADA 41-275.

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 (formerly the Hearing Clerk's office) (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers

Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The agency has determined pursuant to 21 CFR 25.24(d)(1) (proposed December 11, 1979; 44 FR 71742) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended in § 558.630 by revising paragraph (b)(3) to read as follows:

§ 558.630 Tylosin and sulfamethazine.

(b) * * *

(3) To 011490, 016968, 017255, 017274, 024174, 026186, 034500, 035955, 043743, 046987; 10 grams per pound each, paragraph (f)(2)(ii) of this section.

Effective date. This regulation is effective February 3, 1981.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)))

Dated: January 23, 1981.

Gerald B. Guest,

Acting Director, Bureau of Veterinary Medicine.

[FR Doc. 81-3954 Filed 2-2-81; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 1030

Radiological Health; Performance Standards for Microwave and Radio Frequency Emitting Products; Amendments to the Microwave Oven Standard; Measurement and Test Conditions

Correction

In FR Doc. 80-36873, appearing at page 79028 in the issue of Friday, November 28, 1980, make the following changes:

(1) On page 79031, first column, under paragraph (c)(1) of "§ 1030.10 Microwave ovens.", fourth line, "over" should be changed to read "oven".

(2) On page 79031, second column, the effective date, "November 28, 1981" should be changed to read "November 30, 1981".

BILLING CODE 1505-01-M

DEPARTMENT OF LABOR

Wage and Hour Division

29 CFR Part 1

Procedures for Predetermination of Wage Rates

Correction

In FR Doc. 81-1343 appearing at page 4306 in the issue for Friday, January 16, 1981, on page 4314, in § 1.7(b), in the fourth line, after the word "determination" insert a comma.

BILLING CODE 1505-01-M

Office of the Secretary

Mine Safety and Health Administration

Pension and Welfare Benefits Program Office

29 CFR Parts 2, 2520 and 2550

30 CFR Parts 71 and 90

Final Rules; Deferral of Effective Dates

AGENCY: Department of Labor.

ACTION: Final rule; deferral of effective dates.

SUMMARY: This rule defers the effective dates of certain Labor Department regulations until March 30, 1981. This action is taken in response to a January 29, 1981 Memorandum from the President of the United States of America, Ronald Reagan, to the Secretary of Labor and other cabinet officials.

EFFECTIVE DATE: January 29, 1981.

ADDRESSES: Send comments to Gail Lively, Director, Executive Secretariat, Room S2515, Francis Perkins Building, 200 Constitution Avenue, N.W., Washington, D.C. 20210, Attention: *Deferral of Effective Dates*.

FOR FURTHER INFORMATION CONTACT: Donald Smyth, Office of Information, Publications and Reports, Telephone: (202) 523-7316.

SUPPLEMENTARY INFORMATION: By memorandum dated January 29, 1981, attached as an Appendix to this rule and filed with this document, President Ronald Reagan requested that the executive agencies postpone for sixty (60) days the effective date of those final regulations which are currently pending and have not yet become final. This document will formally postpone the effective dates of the below listed rules until March 30, 1981. I take this action because of the reasons stated in the President's Memorandum.