

hour period." Children 5 to 9 years of age: Oral dosage is dibasic sodium phosphate 0.86 to 1.89 g and monobasic sodium phosphate 2.2 to 5.05 g (5 to 10 mL dibasic sodium phosphate/monobasic sodium phosphate oral solution) as a single daily dose. "Do not take more than 10 mL (2 teaspoonfuls) in a 24-hour period." Children under 5 years of age: ask a doctor.

(c) After June 22, 1998, for package size limitation and September 18, 1998, for labeling in accord with paragraph (b) of this section, any such OTC drug product initially introduced or initially delivered for introduction into interstate commerce, or any such drug product that is repackaged or relabeled after these dates regardless of the date the product was manufactured, initially introduced, or initially delivered for introduction into interstate commerce, that is not in compliance with this section is subject to regulatory action.

Dated: April 28, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-12053 Filed 5-20-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; 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 the change of sponsor name from Protiva, a unit of Monsanto, to Monsanto Co.

EFFECTIVE DATE: May 21, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Protiva, a unit of Monsanto has informed FDA of a change of sponsor name to Monsanto Co. Accordingly, FDA is amending 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: 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 "Protiva, A Unit of Monsanto Co." and by alphabetically adding a new entry for "Monsanto Co., 800 North Lindbergh Blvd., St. Louis, MO 63167" and in the table in paragraph (c)(2) in the entry for "059945" by removing the sponsor name "Protiva, A Division of Monsanto Co." and adding in its place "Monsanto Co."

Dated: May 8, 1998.

Andrew J. Beaulieu,

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

[FR Doc. 98-13162 Filed 5-20-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

Animal Drugs, Feeds, and Related Products; Change of Sponsor

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 for 96 new animal drug applications (NADA's) and 4 abbreviated animal drug applications (ANADA's) from Hoffmann-La Roche, Inc., to Roche Vitamins, Inc.

EFFECTIVE DATE: May 21, 1998.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0213.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, has informed FDA that it has transferred the ownership of and all rights and interests in approved NADA's and ANADA's to Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298.

Accordingly, the agency is amending the regulations in 21 CFR parts 510 and 558 to reflect the change of sponsor. The agency is also amending the regulations in § 510.600(c)(1) and (c)(2) by removing Hoffmann-La Roche, Inc., because the sponsor no longer sponsors any approved new animal drugs, and by alphabetically adding an entry for Roche Vitamins, Inc.

List of Subjects

21 CFR Part 510

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

21 CFR Part 558

Animal drugs, Animal feeds.

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 510 and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

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

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for "Hoffmann-La Roche, Inc.," and by alphabetically adding an entry for "Roche Vitamins, Inc.," and in the table in paragraph (c)(2) by removing the entry for "000004" and by numerically adding an entry for "063238" to read as follows:

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

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