

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Part 510

DNR Display Date 6-6-03
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Certifier R. LEDESMA

New Animal Drugs; Change of Sponsor's Name; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor's name from Fort Dodge Animal Health, Division of American Cyanamid Co., to Fort Dodge Animal Health, Division of Wyeth Holdings Corp. The regulations are also being revised to correct the address for Fort Dodge Animal Health, Division of Wyeth.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV-100), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301-827-6967; e-mail: dnewkirk@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Cyanamid Co., P.O. Box 1339, Fort Dodge, IA 50501, has informed FDA of a change of name to Fort Dodge Animal Health, Division of Wyeth Holdings Corp. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect the change.

In addition, when the name of Fort Dodge Animal Health, Division of American Home Products Corp. was changed to Fort Dodge Animal Health, Division of Wyeth (67 FR 67520, November 6, 2002), an inaccurate correction

to the address was made. At this time, it is being changed to the original and correct address.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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.

a. In the table in paragraph (c)(1), in the entry for “Fort Dodge Animal Health, Division of Wyeth” and in the table in paragraph (c)(2), in the entry for “000856” by removing “500” and by adding in its place “800”.

b. In the table in paragraph (c)(1), in the entry for “Fort Dodge Animal Health, Division of American Cyanamid Co.” and in the table in paragraph (c)(2), in the entry for “053501” by removing “American Cyanamid Co.” and by adding in its place “Wyeth Holdings Corp.”.

Dated: May 19, 2003
May 10, 2003.

Steven D. Vaughn DVM

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

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COPY OF THE ORIGINAL**

Steph Alderson