

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 510

DMB
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Certifier R. GEDESMA

New Animal Drugs; Change of Sponsor's 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's name from Vetrepharm Research, Inc., to Bioniche Animal Health USA, Inc.

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: Vetrepharm Research, Inc., 119 Rowe Rd., Athens, GA 30601, has informed FDA of a change of name to Bioniche Animal Health USA, Inc. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c) to reflect this change.

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.

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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.

2. Section 510.600 is amended in the table in paragraph (c)(1) by removing the entry for “Vetrepharm Research, Inc.” and by alphabetically adding an entry for “Bioniche Animal Health USA, Inc.”; and in the table in paragraph (c)(2) by revising the entry for “064847” 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
Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601.	064847

(2) * * *

Drug labeler code	Firm name and address
064847	Bioniche Animal Health USA, Inc., 119 Rowe Rd., Athens, GA 30601

Dated: February 10, 2003
February 10, 2003.

Steven D. Vaughn DVM 02-10-03
Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation,
Center for Veterinary Medicine.
[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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Peggy Sedano