

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 558

New Animal Drugs; 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 an approved abbreviated new animal drug application (ANADA) from Equi Aid Products, Inc., to Farnam Companies, Inc.

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

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-101), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Equi Aid Products, Inc., 1517 West Knudsen Dr., Phoenix, AZ 85027, has informed FDA that it has transferred ownership of, and all rights and interest in, ANADA 200-168 for CW 48 (pyrantel tartrate) Type A medicated article to Farnam Companies, Inc., 301 West Osborn, Phoenix, AZ 85013-3928. Accordingly, the agency is amending the regulations in § 558.485 (21 CFR 558.485) to reflect the transfer of ownership.

Following this change of sponsorship, Equi Aid Products, Inc., is no longer the sponsor of any approved application. Accordingly, § 510.600(c) is amended to remove the entries for Equi Aid Products, Inc.

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

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 [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 “Equi Aid Products, Inc.” and in the table in paragraph (c)(2) by removing the entry for “062240”.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

3. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

§ 558.485 [Amended]

4. Section 558.485 *Pyrantel tartrate* is amended in paragraph (b)(7) by removing “, 017135, and 062240” and by adding in its place “and 017135”.

Dated: 111111111111

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