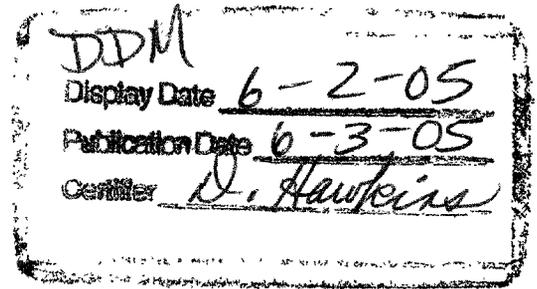


DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520, 522, 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 16 approved new animal drug applications (NADAs) from Purina Mills, Inc., to Virbac AH, 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: david.newkirk@fda.gov.

SUPPLEMENTARY INFORMATION: Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812, has informed FDA that it has transferred ownership of, and all rights and interest in, the following 16 approved NADAs to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137:

TABLE 1.

NADA No.	21 CFR Section	Trade Name
011-779	522.940	Purina Pigemia 100
013-214	558.274	Purina Hygromix-Swine
013-663	520.100a	Purina Liquid Amprol
040-205	520.2380a	Purina Horse Wormer Medicated
042-116	558.185	Purina 6-Day Worm-Kill Feed
042-660	558.630	Purina Pork-Plus Medicated
043-387	558.625	Purina Hog Plus II
046-700	558.365	Statyl

TABLE 1.—Continued

NADA No.	21 CFR Section	Trade Name
049-729	520.2261a	Purina Sulfa
097-258	558.485	Purina Ban Worm For Pigs
099-767	558.630	Purina Tylan 40 Plus Sulfamethazine
113-748	520.1182	Purina Oral Pigemia
132-574	558.325	Purina Check-R-Ton LI
135-941	558.485	Check-E-Ton BM
136-116	520.905d	Purina Worm-A-Rest Litter Pack
140-869	520.1840	Purina Bloat Block; Purina Saf-T-Block BG

Accordingly, the agency is amending the regulations in parts 520, 522, and 558 (21 CFR parts 520, 522, and 558). Sections 520.100a, 520.905d, 520.1182, 520.1840, 520.2261a, 520.2380a, 522.940, 558.185, 558.274, 558.325, 558.365, 558.485, 558.625, and 558.630 will reflect the transfer of ownership and a current format. Sections 520.1182 and 522.940 are being revised to reflect a current format.

In addition, § 520.2380a is being revised to correct the citation for the approved indications for Virbac AH's thiabendazole dewormer approved under NADA 040-205. The citation was corrected in the **Federal Register** of March 3, 1976 (41 FR 9149), but an error was reintroduced in the 1978 printing of the Code of Federal Regulations. This action is being taken to improve the accuracy of the regulations.

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 Parts 520 and 522

Animal drugs.

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 520, 522, and 558 are amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

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

■ 2. Section 520.100a is amended by revising paragraph (b) to read as follows:

§ 520.100a Amprolium drinking water.

* * * * *

(b) *Sponsors.* See Nos. 050604 and 051311 in § 510.600(c) of this chapter.

* * * * *

§ 520.905d [Amended]

■ 3. Section 520.905d is amended in paragraph (b)(2) by removing “017800” and by adding in its place “051311”.

■ 4. Section 520.1182 is revised to read as follows:

§ 520.1182 Iron dextran suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 55.56 milligrams (mg) iron as ferric hydroxide in complex with a low molecular weight dextran.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine—(1) Amount.* Administer 100 mg (1.8 mL) orally by automatic dose dispenser.

(2) *Indications for use.* For the prevention of iron deficiency anemia in baby pigs.

(3) *Limitations.* Treat each pig within 24 hours of farrowing.

§ 520.1840 [Amended]

■ 5. Section 520.1840 is amended in paragraph (b)(2) by removing “017800” and by adding in its place “051311”.

§ 520.2261a [Amended]

■ 6. Section 520.2261a is amended in paragraph (a) by removing “017800” and by adding in its place “051311”.

■ 7. Section 520.2380a is amended by revising the section heading and paragraph (c) to read as follows:

§ 520.2380a Thiabendazole top dressing and mineral protein block.

* * * * *

(c) *Sponsors.* See sponsors in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

(1) No. 051311 for use as in paragraph (e)(1)(i) of this section.

(2) No. 050604 for use as in paragraph (e)(1)(ii) of this section.

(3) No. 021930 for use as in paragraph (e)(2) of this section.

* * * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 8. The authority citation for 21 CFR part 522 continues to read as follows:

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

■ 9. Section 522.940 is revised to read as follows:

§ 522.940 Ferric oxide injection.

(a) *Specifications.* Each milliliter (mL) contains colloidal ferric oxide equivalent to 100 milligrams of iron with a low-viscosity dextrin.

(b) *Sponsors.* See Nos. 051311 and 053501 in § 510.600(c) of this chapter.

(c) *Conditions of use in swine*—(1) For prevention of iron deficiency anemia, administer 1 mL by intramuscular injection at 2 to 5 days of age. Dosage may be repeated at 2 weeks of age.

(2) For treatment of iron deficiency anemia, administer 1 to 2 mL by intramuscular injection at 5 to 28 days of age.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

■ 11. Section 558.185 is amended by revising paragraph (b)(2); and by adding paragraph (b)(3) to read as follows:

§ 558.185 Coumaphos.

* * * * *

(b) * * *

(2) No. 017800 for use of Type A medicated articles containing 11.2 percent coumaphos as in paragraph (e)(1) of this section.

(3) No. 051311 for use of Type A medicated articles containing 1.12 percent coumaphos as in paragraph (e)(1) of this section.

* * * * *

§ 558.274 [Amended]

■ 12. Section 558.274 is amended in paragraph (a)(2) by removing “043733” and by adding in its place “Nos. 043733 and 051311”; and in the table in paragraph (c)(1)(ii) in the “Sponsor” column by adding in numerical sequence “051311”.

§ 558.325 [Amended]

■ 13. Section 558.325 is amended in paragraph (a)(13) by removing “017800” and by adding in its place “051311”; and in paragraphs (d)(2)(ii)(1), (d)(2)(iii)(1), and (d)(2)(iv) in the table in the “Sponsor” column by removing “017800” and by adding in numerical sequence “051311”.

§ 558.365 [Amended]

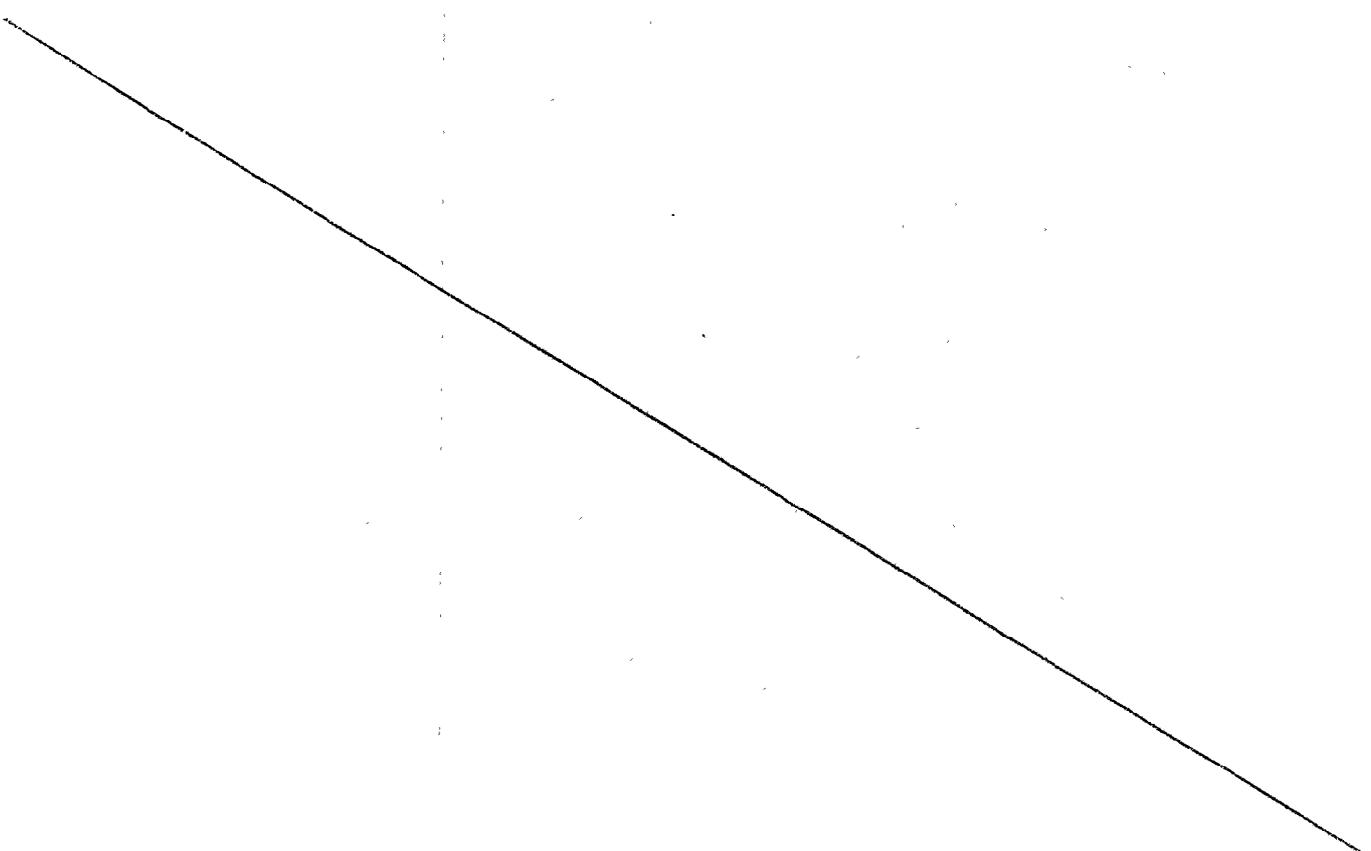
■ 14. Section 558.365 is amended in paragraph (a) by removing “017800” and by adding in its place “No. 051311”.

§ 558.485 [Amended]

■ 15. Section 558.485 is amended in paragraph (b)(5) by removing “017800” and by adding in its place “051311”.

§ 558.625 [Amended]

■ 16. Section 558.625 is amended in paragraph (b)(5) by removing “017800” and by adding in its place “No. 051311”.



§ 558.630 [Amended]

■ 17. Section 558.630 is amended in paragraph (b)(5) by removing "017800" and by adding in its place "No. 051311".

Dated: May 11, 2005
May 11, 2005.

Dr. Steve D. Vaughn

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

SR/Style 5-27-05

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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