

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 520

DDM
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Com: A. Corbin

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 a new animal drug application (NADA) from Akzo Nobel Surface Chemistry AB (Azko Nobel) 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: Akzo Nobel, Box 851, S-44485 Stenungsund, Sweden, has informed FDA that it has transferred ownership of, and all rights and interest in, NADA 10-886 for Purina Liquid Wormer to Virbac AH, Inc., 3200 Meacham Blvd., Ft. Worth, TX 76137.

Following this change of sponsorship, Akzo Nobel is no longer the sponsor of an approved application. Accordingly, 21 CFR 510.600(c) is being amended to remove the entries for Akzo Nobel.

Purina Liquid Wormer (NADA 10-886) is labeled for use in chickens, turkeys, and swine. The drug was the subject of a National Academy of Sciences/National Research Council evaluation of effectiveness under FDA's

drug efficacy study implementation (DESI) program (DESI 10–005V). The findings of the evaluation were published in the **Federal Register** of February 14, 1969 (34 FR 2213). A separate entry in part 520 (21 CFR part 520) (§ 520.1807) was created (64 FR 23017, April 29, 1999) to accommodate oral piperazine products approved for use in chickens, turkeys, and swine consistent with DESI findings and human food safety requirements (DESI finalization). However to date, NADA 10–886 has not been DESI finalized. Accordingly, § 520.1807 will not be amended to reflect the approval of NADA 10–886 until the current sponsor of that NADA submits a supplemental NADA adequate for DESI finalization.

In addition, § 520.1806 has been found to inaccurately list Akzo Nobel as the sponsor of an oral piperazine product approved for use in dogs. This error occurred during the codification of a previous change of sponsor for NADA 10–886 (59 FR 28763, June 3, 1994). Accordingly, the agency is amending the regulations in § 520.1806 to remove Akzo Nobel’s drug labeler code and to reflect the current format.

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 520

Animal drugs.

■ 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 520 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 is amended in the table in paragraph (c)(1) by removing the entry for “Akzo Nobel Surface Chemistry AB” and in the table in paragraph (c)(2) by removing the entry for “063765”.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

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

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

■ 4. Section 520.1806 is revised to read as follows:

§ 520.1806 Piperazine suspension.

(a) *Specifications.* Each milliliter of suspension contains piperazine monohydrochloride equivalent to 33.5 milligrams (mg) piperazine base.

(b) *Sponsor.* See No. 017135 in § 510.600(c) of this chapter.

(c) *Special considerations.* See § 500.25(c) of this chapter.

(d) *Conditions of use in dogs—(1) Indications for use.* For the removal of roundworms (*Toxocara canis* and *Toxascaris leonina*).

(2) *Dosage.* Administer 20 to 30 mg piperazine base per pound body weight as a single dose.

(3) *Limitations.* Administer by mixing into the animal's ration to be consumed at one feeding. For animals in heavily contaminated areas, reworm at monthly intervals. Not for use in unweaned pups or animals less than 3 weeks of age.

Dated: December 10, 2004
December 10, 2004.

Steven D. Vaughn

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

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