

animal drug applications (NADAs) from Anthony Products Co. to Cross Vetpharm Group Ltd.

**DATES:** This rule is effective June 10, 2003.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** Anthony Products Co., 5600 Peck Rd., Arcadia, CA 91006, has informed FDA that it has transferred ownership of, and all rights and interest in, the following two approved NADAs to Cross Vetpharm Group, Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland:

NADA Number	Trade Name
065-505	MICROCILLIN Injectable Suspension
065-506	COMBICILLIN Injectable Suspension

Accordingly, the agency is amending the regulations in 21 CFR 522.1696a and 522.1696b to reflect the transfer of ownership.

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 522**

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 part 522 is amended as follows:

**PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS**

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

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

**§ 522.1696a [Amended]**

■ 2. Section 522.1696a *Penicillin G benzathine and penicillin G procaine sterile suspension* is amended in paragraph (b)(1) by removing "000864, 010515, and 049185" and by adding in its place "010515, 049185, and 061623"; and in paragraph (b)(3) by removing "000864, 010515, and 059130" and by adding in its place "010515, 059130, and 061623".

**§ 522.1696b [Amended]**

■ 3. Section 522.1696b *Penicillin G procaine aqueous suspension* is amended in paragraph (b)(2) by removing "000864 and 055529" and by adding in its place "055529 and 061623"; in paragraph (d)(2)(i)(A) by removing "000864, 010515, 053501, and 059130" and by adding in its place "010515, 053501, 059130, and 061623"; and in paragraph (d)(2)(iii)(A) by removing "000864, 010515, 053501, and 059130" and by adding in its place "010515, 053501, and 059130".

Dated: May 19, 2003.

**Steven D. Vaughn,**

*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Fenbendazole.**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Intervet, Inc. The supplemental NADA provides for use of an approved fenbendazole Type A medicated article to make Type B and Type C medicated feeds used for the control of gastrointestinal worms in horses.

**DATES:** This rule is effective June 10, 2003.

**FOR FURTHER INFORMATION CONTACT:**

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**SUPPLEMENTARY INFORMATION:** Intervet, Inc., P.O. Box 318, 405 State St., Millsboro, DE 19966, filed a supplement to NADA 131-675 that provides for the use of SAFE-GUARD (fenbendazole) 20% Type A medicated article to make Type B and Type C medicated horse feeds. The medicated feeds are used for the control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*, *Triodontophorus* spp.), small strongyles (*Cyathostomum* spp.,

*Cylicocyclus* spp., *Cylicostephanus* spp.), pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses. The NADA is approved as of March 14, 2003, and the regulations are amended in 21 CFR 558.258 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning March 14, 2003.

The agency has determined under § 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

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 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 part 558 is amended as follows:

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

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

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

■ 2. Section 558.258 is amended by redesignating paragraph (e)(4) as paragraph (e)(5) and by adding new paragraph (e)(4) to read as follows:

**§ 558.258 Fenbendazole.**

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(e) \* \* \*

(4) Horses.