

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:

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: 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.

[FR Doc. 03-14547 Filed 6-9-03; 8:45 am]

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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:

Melanie R. Berson, Center for Veterinary Medicine (HFV-110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7540, e-mail: mberson@cvm.fda.gov.

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.

* * * * *

(e) * * *

(4) Horses.

Amount fenbendazole in grams per ton	Indications for use	Limitations	Sponsor
(i) 4,540	5 mg/kg body weight (2.27 mg/lb) for the control of large strongyles (<i>Strongylus edentatus</i> , <i>S. equinus</i> , <i>S. vulgaris</i> , <i>Triodontophorus</i> spp.), small strongyles (<i>Cyathostomum</i> spp., <i>Cylicocyclus</i> spp., <i>Cylicostephanus</i> spp.), and pinworms (<i>Oxyuris equi</i>); 10 mg/kg body weight (4.54 mg/lb) for the control of ascarids (<i>Parascaris equorum</i>).	Feed at the rate of 0.1 lb of feed per 100 lb of body weight to provide 2.27 mg fenbendazole/lb of body weight in a 1-day treatment or 0.2 lb of feed per 100 lb of body weight to provide 4.54 mg fenbendazole/lb of body weight in a 1-day treatment. All horses must be eating normally to ensure that each animal consumes an adequate amount of the medicated feed. Regular deworming at intervals of 6 to 8 weeks may be required due to the possibility of reinfection. Do not use in horses intended for food.	057926
(ii) [Reserved]			

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Dated: May 27, 2003.

Stephen F. Sundlof,*Director, Center for Veterinary Medicine.*

[FR Doc. 03-14545 Filed 6-9-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117**

[CGD07-03-087]

Drawbridge Operation Regulations; NE. 8th Street (George Bush Boulevard) Bridge, Atlantic Intracoastal Waterway, Mile 1038.7, Delray Beach, Palm Beach County, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Seventh Coast Guard District, has approved a temporary deviation from the regulations governing the operation of the NE. 8th Street (George Bush Boulevard) bridge at Delray Beach across the Atlantic Intracoastal Waterway, mile 1038.7 in Delray Beach, Palm Beach County, Florida. Under this deviation, the bridge need only open a single-leaf of the bridge and shall provide double-leaf openings with two-hours advance notice to the bridge tender. This temporary deviation is required to allow the bridge owner to safely complete repairs to the bridge.

DATES: This deviation is effective from 7 a.m. on June 16, 2003, until 6 p.m. on August 16, 2003.

ADDRESSES: Material received from the public, as well as comments indicated in this preamble as being available in the docket, are part of docket [CGD07-

03-087] and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, Florida 33131 between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Manager, Seventh Coast Guard District, Bridge Branch at (305) 415-6744.

SUPPLEMENTARY INFORMATION: The existing regulations of the NE. 8th Street bridge, mile 1038.7 at Delray Beach require the bridge to open on signal; except that, from November 1 to May 31, from 11 a.m. to 6 p.m., on Saturdays, Sundays and Federal holidays, the draw need open only on the hour, quarter-hour, half-hour, and three quarter-hour. On May 7, 2003, Palm Beach County, the bridge owner, requested a deviation from the current regulations to allow the bridge to only open a single-leaf of the bridge. Double-leaf openings are available with two-hours advance notice to the bridge tender. The other leaf of the bridge will remain in the upright, open to navigation position. This schedule will be in effect from 7 a.m. on June 16, 2003, to 6 p.m. on July 3, 2003, and from 7 a.m. on July 8, 2003, to 6 p.m. on August 16, 2003. During all other times, the bridge will open according to the published schedule in 33 CFR 117.261(z). This temporary deviation is required to allow the bridge owner to safely complete repairs to the bridge structure.

The District Commander has granted a temporary deviation from the operating requirements listed in 33 CFR 117.261(z). Under this deviation, the NE. 8th Street (George Bush Boulevard) bridge need only open a single-leaf of the bridge from 7 a.m. on June 16, 2003, to 6 p.m. on July 3, 2003, and from 7 a.m. on July 8, 2003, to 6 p.m. on August 16, 2003. During this time the

bridge shall provide double-leaf openings with two-hours advance notice to the bridge tender.

Dated: May 29, 2003.

Greg Shapley,*Chief, Bridge Administration, Seventh Coast Guard District.*

[FR Doc. 03-14590 Filed 6-9-03; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 165**

[CGD09-03-217]

RIN 1625-AA00

Safety Zone; Grosse Point Shores, Lake St. Clair, MI

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for the Celebrate America fireworks display on June 14, 2003. This safety zone is necessary to control vessel traffic within the immediate location of the fireworks launch site and to ensure the safety of life and property during the event. This safety zone is intended to restrict vessel traffic from a portion of Lake St. Clair.

DATES: This temporary final rule is effective from 8 p.m. until 11 p.m. on June 14, 2003.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD09-03-217] and are available for inspection or copying at: U.S. Coast Guard Marine Safety Office Detroit, 110 Mt. Elliott Ave. Detroit, MI 48207, between 8 a.m. and 4 p.m.,