

may be seen in the Division of Dockets Management (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.

The agency has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 522

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under the 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.

■ 2. Section 522.2476 is amended by removing paragraph (a); by redesignating paragraphs (b), (c), and (d) as paragraphs (a), (b), and (c); and by revising newly redesignated paragraphs (a)(1), (a)(2), (c)(1)(iii), and (c)(2)(iii) to read as follows:

§ 522.2476 Trenbolone acetate.

(a) * * *

(1) No. 021641 for use as in paragraph (c) of this section.

(2) No. 057926 for use as in paragraphs (c)(1)(i)(A), (c)(1)(ii), (c)(1)(iii), (c)(2)(i)(A), (c)(2)(ii), and (c)(2)(iii) of this section.

* * * * *

(c) * * *

(1) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

(2) * * *

(iii) *Limitations.* Implant subcutaneously in ear only. Do not use

in animals intended for subsequent breeding or in dairy animals. Safety and effectiveness have not been established in veal calves. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

Dated: November 18, 2004.

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; Coumaphos

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to remove conditions of use in cattle and chickens for a coumaphos Type A medicated article for which approval was withdrawn in July 1996. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective December 2, 2004.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV-6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-4567, e-mail: george.haibel@fda.gov.

SUPPLEMENTARY INFORMATION: FDA has found that parts 500 to 599 (21 CFR parts 500 to 599) of the Code of Federal Regulations reflect conditions of use in cattle for a coumaphos Type A medicated article for which approval was withdrawn by FDA, at the sponsors request, on July 3, 1996 (61 FR 34727). At this time, FDA is amending the regulations in § 558.185 to reflect the remaining approved uses of coumaphos in medicated cattle feeds.

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 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 558.185 is amended by redesignating paragraph (d) as paragraph (e); by revising paragraphs (a), (b), and newly redesignated (e)(1); and by adding paragraph (d) to read as follows:

§ 558.185 Coumaphos.

(a) *Specifications.* Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos.

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

(1) No. 000859 for use of Type A medicated articles containing 1.12, 2.0, 11.2, or 50 percent coumaphos as in paragraphs (e)(2) and (e)(3) of this section.

(2) No. 017800 for use of Type A medicated articles containing 1.12 or 11.2 percent coumaphos as in paragraph (e)(1) of this section.

* * * * *

(d) *Special considerations.* Labeling shall bear the following caution statement: "The active ingredient coumaphos is a cholinesterase inhibitor. Do not use this product on animals simultaneously or within a few days before or after treatment with or exposure to cholinesterase-inhibiting drugs, pesticides, or chemicals." Also, see § 500.25 of this chapter.

(e) *Conditions of use—(1) Beef and dairy cattle—(i) Amount.* 0.0002 lb. (0.091 gram) per 100 lb. body weight per day for 6 consecutive days. Should conditions warrant, repeat treatment at 30-day intervals.

(ii) *Indications for use.* Control of gastrointestinal roundworms (*Haemonchus* spp., *Ostertagia* spp., *Cooperia* spp., *Nematodirus* spp., *Trichostrongylus* spp.).

(iii) *Limitations.* Feed in the normal grain ration to which the animals are accustomed, but not in rations containing more than 0.1 percent coumaphos. Do not feed to animals less than 3 months old. Do not feed to sick animals or animals under stress, such as those just shipped, dehorned, castrated, or weaned within the last 3 weeks. Do not feed in conjunction with oral

drenches or with feeds containing phenothiazine.

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Dated: November 16, 2004.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD05-04-117]

RIN 1625-AA09

Drawbridge Operation Regulation: Atlantic Intracoastal Waterway, Elizabeth River (Southern Branch), VA

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the operating regulations for the Norfolk Southern (NS) #7 Railroad Bridge at Atlantic Intracoastal Waterway (AICW) mile 5.8, in Chesapeake, Virginia. The final rule for the NS Railroad Bridge will eliminate the need for a bridge tender by allowing the bridge to remain in the fully open position, to be operated from a remote location, and to close the bridge for train crossings and periodic repairs. The final rule will provide for the reasonable needs of navigation.

DATES: This rule is effective January 3, 2005.

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 CGD05-04-117 and are available for inspection or copying at Commander (obr), Fifth Coast Guard District, Federal Building, 1st Floor, 431 Crawford Street, Portsmouth, Virginia 23704-5004 between 8 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Waverly W. Gregory, Jr., Bridge Administrator, Fifth Coast Guard District, at (757) 398-6222.

SUPPLEMENTARY INFORMATION:

Regulatory History

On August 27, 2004, we published a notice of proposed rulemaking (NPRM) entitled "Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, Elizabeth River (Southern Branch), VA" in the **Federal Register**

(69 FR 52617). We received four letters commenting on the proposed rule. No public hearing was requested nor held.

Background and Purpose

Norfolk Southern Corporation (NSC) requested a change to the current operating regulation set out in 33 CFR 117.5 that requires the drawbridge to open promptly and fully for the passage of vessels when a request to open is given.

NSC would remotely control the opening and closing of the Norfolk Southern (NS) #7 Railroad Bridge across the Southern Branch of the Elizabeth River at AICW mile 5.8 in Chesapeake, Virginia, by the remote operator at the NS #5 Railroad Bridge across the Eastern Branch of the Elizabeth River, at mile 1.1, in Norfolk, Virginia. NSC installed a Programmable Logic Controller and associated mechanical, electrical and signal apparatus on the drawbridge. NSC has installed motion sensors, laser scanners and high-resolution video cameras on the bridge to enhance the remote operator's ability to monitor and control the equipment. The NS #5 Railroad Bridge office, in Norfolk, is also equipped with an amplified open-mike from the bridge to enable the remote operator to hear boat horns that may signal for an opening. NS has also installed additional safety warning lights to the bridge for the remote operation.

Under this rule, the drawbridge would be left in open position to vessels and would only close for the passage of trains and to perform periodic maintenance authorized in accordance with subpart A of part 117.

Before the NS #7 Railroad Bridge closes for any reason, the remote operator will observe the waterway traffic in the area with closed-circuit cameras and motion sensors mounted on the bridge. The bridge would only be closed if the off-site remote operator's visual inspection shows that the channel is clear and there are no vessels transiting the area.

While the NS #7 Railroad Bridge is moving from the full open position to the full closed position, the off-site remote operator will maintain constant surveillance of the navigation channel to ensure that no conflict with maritime traffic exists. In the event of failure or obstruction, the off-site remote operator will stop and return the bridge to the full open position to vessels. In these situations, a bridge tender must be called and must be on-site within 30 minutes to operate the bridge.

During span movement, the channel traffic lights will flash red, the horn would sound twice, and an audio voice-

warning device will announce bridge movement, then two repeat blasts of the horn will continue until the bridge is seated and locked down. When the bridge is seated and locked down to vessels, the channel traffic lights will flash red.

When the rail traffic has cleared, the horn will automatically sound five times to indicate that the draw of the NS #7 Railroad Bridge is about to return to the full open position to vessels. During the open span movement, the channel traffic lights will flash red, the horn will sound twice, followed by a pause, and then five repeat blasts of the horn until the bridge is in the full open position to vessels. In the full open position to vessels, the bridge channel traffic lights will flash green then an audio warning device will announce bridge movement by stating "Security, security, security, the NS #7 Railroad Bridge at mile 5.8 is open for river traffic". After the train has cleared the bridge by leaving the track circuit, any delay in opening of the draw to vessels shall not exceed ten minutes except as provided in 33 CFR 117.31(b). Operational information will be provided 24 hours a day on marine channel 13 and via telephone (757) 924-5320.

This rule will make the closure process of the NS #7 Railroad Bridge be more efficient during train crossings and periodic maintenance and will save operational costs by eliminating bridge tenders while providing greater bridge operating capabilities.

Discussion of Comments and Changes

The Coast Guard received four comments on the NPRM. Three comments, from commercial vessel operators, expressed their concerns with the location of the off-site remote operation. Their interests centered around the limited effectiveness of monitoring and communications with approaching vessels, their past experience with current bridge tenders' failure to respond to security calls, the lowering of the bridge while their vessels are transiting, and the loss of on-site bridge tenders controlling the operation of the bridge.

The remaining comment, offered by NSC, addressed the commercial vessel operators' concerns. NSC indicated that the location of the Norfolk area bridge operation center at the NS #5 Railroad Bridge office was selected because of the better-quality operators' house and facilities, economic considerations for relocation and that the communication between marine interests and the NS #5 Railroad Bridge operator will be comparable to the communication with the NS #7 Railroad Bridge operator. The