

**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 Fermenta Animal Health Co. The supplement provides for use of fixed combination Type A medicated articles containing chlortetracycline, sulfathiazole, and penicillin in making Type B and C medicated swine feeds for swine from 10 pounds to 6 weeks post-weaning.

**EFFECTIVE DATE:** January 26, 1996.

**FOR FURTHER INFORMATION CONTACT:**

James F. McCormack, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1607.

**SUPPLEMENTARY INFORMATION:** Fermenta Animal Health Co., 10150 North Executive Hills Blvd., Kansas City, MO 64153, filed a supplement to NADA 39-077 CSP™ 250 (20 grams (g) of chlortetracycline (as the hydrochloride), 20 g of sulfathiazole, and 10 g of penicillin (as penicillin procaine), per pound) and CSP™ 500 (40 g of chlortetracycline (as the hydrochloride), 40 g of sulfathiazole, and 20 g of penicillin (as penicillin procaine), per pound). The NADA provides for use of fixed combination Type A medicated articles to make Type B and C medicated swine feeds for prestarter, starter, grower, and finisher rations. The supplement provides for prestarter and starter rations to be given to swine from 10 pounds of body weight to 6 weeks postweaning for reduction of incidence of cervical abscesses, treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery), maintenance of weight gains in the presence of atrophic rhinitis, increased rate of weight gain and improved feed efficiency. The supplement is approved as of January 26, 1996, and the regulations are amended in § 558.155 (21 CFR 558.155) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, the agency is revising the section heading for § 558.155 to reflect the active ingredients as on the label, i.e., that the product is known as chlortetracycline with sulfathiazole and penicillin, not as chlortetracycline hydrochloride with procaine penicillin and sulfathiazole. The approvals paragraph does specify the salts and esters approved for use.

In § 558.155(d) the feed consumption table is removed. The performance or therapeutic claims of the product are based on *ad libitum* consumption and

not the minimum desired daily feed intake consumption values reported in the table. This, together with changes in weaning weights, renders the table obsolete. Also, the indications for use are editorially revised to clarify the indications for each feeding group.

The product, chlortetracycline, sulfathiazole, and penicillin, in combination in a Type A medicated article, is a new animal drug used to make Type B and Type C medicated feeds. As provided in § 558.4(b), the combination drug product is a Category II drug because it requires a withdrawal period at its lowest continuous use level. Therefore, it requires an approved Form FDA 1900 for making Type B or Type C medicated feeds as in approved NADA 39-077 and in § 558.155.

In accordance with the freedom of information provisions of part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval does not qualify for marketing exclusivity because the supplement does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) or human food safety studies (other than bioequivalence or residue studies) essential to the approval and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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.

**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: Sec. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.155 is amended by revising the section heading and paragraphs (d)(2) and (d)(3) to read as follows:

**§ 558.155 Chlortetracycline, sulfathiazole, penicillin.**

\* \* \* \* \*

(d) \* \* \*

(2) *Indications for use.* For reduction of incidence of cervical abscesses. Treatment of bacterial enteritis (salmonellosis or necrotic enteritis caused by *Salmonella choleraesuis* and vibronic dysentery). Maintenance of weight gains in the presence of atrophic rhinitis. Swine 10 pounds of body weight to 6 weeks post-weaning: Increased rate of weight gain and improved feed efficiency. Swine 6 to 16 weeks post-weaning: Increased rate of weight gain.

(3) *Limitations.* For swine raised in confinement (dry-lot) or on limited pasture. Feed as sole ration. Withdraw 7 days prior to slaughter.

Dated: January 3, 1996.

Robert C. Livingston,  
Director, Office of New Animal Drug  
Evaluation, Center for Veterinary Medicine.  
[FR Doc. 96-1323 Filed 1-25-96; 8:45 am]

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**DEPARTMENT OF TRANSPORTATION**

**Coast Guard**

**33 CFR Part 165**

[CGD02-95-003]

RIN 2115-AE84

**Regulated Navigation Area; Ohio River Mile 466.0 to Mile 473.0**

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is establishing a regulated navigation area on the Ohio River in the Cincinnati, OH area. The rule is needed to control vessel traffic while transiting downbound at night during high water conditions in the regulated area. The rule will restrict commercial navigation in the regulated area for the safety of vessel traffic and the protection of life and property along the river.

**EFFECTIVE DATE:** This rule is effective February 26, 1996.

**ADDRESSES:** The Commanding Officer, U.S. Coast Guard Marine Safety Office, Louisville, KY, maintains the public docket for this rule. The documents and

other materials referenced in this notice will be available for inspection at the U.S. Coast Guard Marine Safety Office, 600 Martin Luther King Place, Room 360, Louisville, KY 40202-2230. Normal office hours are between 7:30 a.m. and 4 p.m., Monday through Friday, except holidays.

**FOR FURTHER INFORMATION CONTACT:**

Lieutenant Gregory A. Howard, Project Officer, U.S. Coast Guard Marine Safety Office, Louisville, Kentucky at (502) 582-5194.

**SUPPLEMENTARY INFORMATION:**

Drafting Information: The principal persons involved in drafting this document are Lieutenant Gregory A. Howard, Project Officer for the Captain of the Port, Louisville, Kentucky (502) 582-5196 and Lieutenant S. Moody, Project Attorney, Second Coast Guard District Legal Office, St. Louis, MO (314) 539-3900.

**Background and Purpose**

On May 16, 1995 the Notice of Proposed Rule Making was published in the Federal Register at 60 FR 26012. No comments were received from the date of publication of the proposed rule until the end of the comment period on July 17, 1995. Therefore the Coast Guard is establishing this regulated navigation area by this final rule with only a minor change to the proposed rule.

The situation requiring this regulation is periodic high water conditions on the Ohio River in the vicinity of Cincinnati, Ohio. The Ohio River in the Cincinnati area is hazardous to transit under the best conditions. To transit the area, mariners must navigate through several sweeping turns and seven bridges. When the water level in the Ohio River reaches 45 feet on the Cincinnati gauge, river currents increase and become very unpredictable, making it difficult for downbound vessels to maintain steerageway. During the period of 1983-1993 there were 13 marine casualties involving towboats from mile 468.5 to mile 473.0 on the Ohio River. A review of the case documentation showed that seven of the thirteen cases mentioned high water specifically or used terms such as "swift current" or "heavy current" as contributing factors to the casualties. Nine of these cases involved tows greater than 600 feet in length; six of the cases involved downbound tows; and five cases occurred at night. During hours of darkness the background lights of the city of Cincinnati hamper mariners' ability to maintain sight of the front of their tow. This rule is intended to protect the public and the environment, at night during periods of high water, from a potential hazard of large downbound tows carrying

hazardous material through the regulated area.

In the past, the Captain of the Port, Louisville, Kentucky has responded to this hazard by issuing a Temporary Final Rule to establish a Safety Zone in the area when warranted by high water conditions. This rule is intended to establish a permanent Regulated Navigation Area in which restrictions are activated and deactivated as a function of river level. The number of days that traffic will be affected by this rule will vary from several days to several weeks depending on the river levels. A permanent Regulated Navigation Area will permit vessels and commerce using the Ohio River to plan and schedule their tow traffic accordingly.

**Discussion of Regulations**

This rule would establish a Regulated Navigation Area on the Ohio River in the Cincinnati, Ohio area. The restrictions for the Regulated Navigation Area will only be in effect from one-half hour before sunset to one-half hour after sunrise whenever the river level is at or above 45 on the Cincinnati gauge. The rule prohibits transit by downbound tows containing cargoes regulated by title 46 Code of Federal Regulations Subchapter D and O which have a tow length exceeding 600 feet in length not including the tow boat; requires all commercial vessels in the regulated navigation area to monitor VHF-FM radiotelephone Channel 13; requires all downbound commercial vessels to attempt to contact other vessels in the regulated navigation area shortly before entering the area (this is a change from the Notice of Proposed Rule Making which required contact shortly after entering the area); and prohibits vessels from loitering in the navigation channel.

Since the water level of the Ohio River is seasonal and not predictable, establishing fixed calendar dates for the regulation is not practical. The rule is structured to permit the Captain of the Port, Louisville, Kentucky to activate or deactivate the regulated navigable area by issuing the proper notices. Broadcast Notice to Mariners will be issued in anticipation of high water, then again when the river reaches 45 feet, and then a termination broadcast will be issued when the river falls below 45 feet.

These regulations are needed due to the hazardous conditions that exist for all vessels transiting the Cincinnati area when the Ohio River is at high water during hours of darkness.

**Regulatory Evaluation**

This rule is not a significant regulatory action under section 3(f) of

Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

**Small Entities**

Under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632).

Because it expects the impact of this rule to be minimal, the Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

**Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

**Federalism Assessment**

The Coast Guard has analyzed this rule in accordance with the principles and criteria of Executive Order 12612, and has determined that this rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

**Environmental Assessment**

The Coast Guard considered the environmental impact of this rule and concluded that, under section 2.B.2 of Commandant Instruction M16475.1B, as revised by 59 FR 38654; July 29, 1994, this rule is categorically excluded from further environmental documentation as an action required to protect the public and the environment.

**List of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (Water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons set out in the preamble, The Coast Guard amends

Subpart F of Part 165 of Title 33, Code of Federal Regulations, as follows:

#### **PART 165—[AMENDED]**

1. The authority citation for Part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. A new § 165.205 is added to read as follows:

##### **§ 165.205 Ohio River at Cincinnati, OH; regulated navigation area.**

(a) *Location.* The following is a regulated navigation area (RNA)—The waters of the Ohio River between mile 466.0 and mile 473.0.

(b) *Activation.* The restrictions in paragraphs (c) (i) through (iv) are in effect from one-half hour before sunset to one-half hour after sunrise when the Cincinnati, Ohio, Ohio River Gauge is at or above the 45 foot level. The Captain of the Port, Louisville, Kentucky will publish a notice in the Local Notice to Mariners and will make announcements by Coast Guard Marine Information Broadcasts whenever the river level measured at the gauge activates or terminates the navigation restrictions in this section.

(c) *Regulations.*

(i) Transit through the RNA by all downbound vessels towing cargoes regulated by Title 46 Code of Federal Regulations Subchapters D and O with a tow length exceeding 600 feet excluding the tow boat is prohibited.

(ii) No vessel shall loiter, anchor, stop, remain or drift without power at any time within the navigation channel of the RNA.

(iii) All commercial vessels shall continually monitor VHF–FM channel 13 on their radiotelephone while in or approaching the RNA.

(iv) Between Ohio River miles 464.0 and 466.0, downbound vessels shall make a broadcast in the blind, on VHF–FM channel 13 announcing their estimated time of entering the RNA.

Dated: January 9, 1996.

Paul M. Blayney,

*Rear Admiral, U.S. Coast Guard, Commander, Second Coast Guard District, St. Louis, MO.*

[FR Doc. 96–1386 Filed 1–25–96; 8:45 am]

BILLING CODE 4910–14–M

#### **33 CFR Part 165**

[COTP Louisville 96–001]

RIN 2115–AA97

#### **Safety Zone; Ohio River, Cincinnati, OH**

AGENCY: Coast Guard, DOT.

**ACTION:** Temporary rule.

**SUMMARY:** The Coast Guard is establishing a temporary safety zone on the Ohio River. The regulation is needed to control commercial vessel traffic in the regulated area while transiting downbound at night during high water conditions. The regulation will restrict commercial navigation in the regulated area for the safety of vessel traffic and the protection of life and property along the river.

**EFFECTIVE DATES:** This regulation is effective on January 19, 1996, at 2 p.m. est. It will terminate at 8 a.m. est. on February 1, 1996, unless sooner terminated by the Captain of the Port Louisville, Kentucky.

**FOR FURTHER INFORMATION CONTACT:** LT Paul D. Thorne, Supervisor, Coast Guard Marine Safety Detachment, Cincinnati, Ohio at (513) 922–3820.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background and Purpose**

The situation requiring this regulation is high water in the Ohio River in the vicinity of Cincinnati, Ohio. The Ohio River in the Cincinnati area is hazardous to transit under the best conditions. To transit the area, mariners must navigate through several sweeping turns and seven bridges. When the water level in the Ohio River reaches 45 feet, on the Cincinnati gage, river currents increase and become very unpredictable, making it difficult for downbound vessels to maintain steerageway. During hours of darkness the background lights of the city of Cincinnati hamper mariners' ability to maintain sight of the front of their tow. The regulation is intended to protect the public and the environment, at night during periods of high water, from a potential hazard of large downbound tows carrying hazardous material through the regulated area.

In accordance with 5 U.S.C. 553, a notice of proposed rulemaking has not been published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impracticable. Specifically, the high water periods in the Cincinnati, Ohio, area are natural events which cannot be predicted with any reasonable accuracy. The Coast Guard deems it to be in the public's best interest to issue a regulation now, as the situation presents an immediate hazard to navigation, life, and property.

##### **Regulatory Evaluation**

This rule is not a significant regulatory action under section 3(f) of

Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not under the regulatory policies and procedures of the Department of Transportation (DOT) (44 FR 11040; February 26, 1979). Because the duration of this emergency situation is anticipated to be short, the Coast Guard expects the economic impact of this regulation to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

To avoid any unnecessary adverse economic impact on businesses which use the river for commercial purposes, Captain of the Port Louisville, Kentucky, will monitor river conditions and will authorize entry of restricted vessels into the regulated area as conditions permit. Changes will be announced by Marine Safety Information Radio broadcast (Broadcast Notice to Mariners) on VHF marine band radio, channel 22 (157.1 MHz). Mariners may also call LT Paul D. Thorne, Supervisor, Coast Guard Marine Safety Detachment, Cincinnati, Ohio at (513) 922–3820 for current information.

##### **Collection of Information**

This rule contains no collection of information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

##### **Federalism Assessment**

The Coast Guard has analyzed this regulation under the principles and criteria contained in Executive Order 12612 and has determined that it does not raise sufficient federalism implications to warrant the preparation of a Federalism Assessment.

##### **Environment**

The Coast Guard considered the environmental impact of this regulation and concluded that, under section 2.B.2. of Commandant Instruction M16475.1B, this rule is categorically excluded from further environmental documentation.

##### **Lists of Subjects in 33 CFR Part 165**

Harbors, Marine safety, Navigation (water), Reporting and recordkeeping requirements, Security measures, Waterways.

For the reasons set out in the preamble, the Coast Guard amends 33 CFR Part 165 as follows:

1. The authority citation for Part 165 continues to read as follows: