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Dated: April 4, 2003.

Steven D. Vaughn,

Director, Office of New Animal Drug
Evaluation, Center for Veterinary Medicine.
[FR Doc. 03-10416 Filed 4-25-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline and Sulfamethazine

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 an abbreviated new animal drug application (ANADA) filed by Pennfield Oil Co. The ANADA provides for the use of a fixed-combination Type A medicated article containing chlortetracycline and sulfamethazine to make two-way combination drug Type C medicated feeds for beef cattle.

DATES: This rule is effective April 28, 2003.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed ANADA 200-314 for use of PENNCHLOR S 700 (chlortetracycline/sulfamethazine), a fixed-combination Type A medicated article used to make two-way combination drug Type C medicated feeds for beef cattle. Pennfield Oil Co.'s PENNCHLOR S 700 Type A medicated article is approved as a generic copy of Alpharma Inc.'s AUREO S 700, approved under NADA 35-805. The ANADA is approved as of January 29, 2003, and the regulations are amended in 21 CFR 558.140 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.

The agency has determined under 21 CFR 25.33(a)(2) 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.

§ 558.140 [Amended]

■ 2. Section 558.140 *Chlortetracycline and sulfamethazine* is amended in paragraph (a) by removing "046573" and by adding in its place "Nos. 046573 and 053389".

Dated: April 1, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-10418 Filed 4-25-03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07-03-048]

RIN 1625-AA09

Drawbridge Operation Regulations; Atlantic Intracoastal Waterway, Miles 1062.6 and 1064.0 at Fort Lauderdale, Broward County, FL

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is temporarily changing the regulations governing the operation of the East Sunrise Boulevard (SR 838) and East Las Olas bridges, miles 1062.6 and 1064.0, in Fort Lauderdale, Florida. This temporary rule allows these bridges to not open for periods of time on May 3 and 4, 2003, to facilitate the vehicle traffic flow to and from the Air & Sea Show, while still providing for the reasonable needs of navigation.

DATES: This rule is effective from 4 p.m. on May 3 to 6 p.m. on May 4, 2003.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of this docket and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, 909 SE. 1st Avenue, Room 432, Miami, FL 33131 between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

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

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NRPM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM for this regulation. Publishing an NPRM was impracticable and contrary to the public interest. There was insufficient time remaining to publish an NPRM after we received this request to change the bridges' operating schedules, and further delaying the event to follow normal rulemaking procedures before incorporating this important safety measure would have a significant negative effect on the outcome of this highly-attended event.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. We did not receive this request to change the bridges' operating schedules with sufficient time remaining to delay the rule's effectiveness until 30 days after its publication. Further, delaying the event to follow normal rulemaking procedures before incorporating this important safety measure would have a significant negative effect on the outcome of this highly-attended event.

Background and Purpose

The East Las Olas Boulevard bridge, mile 1064.0, has a vertical clearance of 31 feet above mean high water and a horizontal clearance of 91 feet between

the fenders. The existing regulations in 33 CFR 117.5 require the bridge to open on signal.

The East Sunrise Boulevard bridge (SR 838), mile 1062.6, has a vertical clearance of 25 feet at mean high water and a horizontal clearance of 90 feet between the fenders. The existing regulation is 33 CFR 117.261(gg) and requires the bridge to open on signal; except that from November 15 to May 15, from 10 a.m. to 6 p.m., the draw need open only on the hour, quarter-hour, half-hour and three-quarter hour.

The City of Fort Lauderdale Police Department, on behalf of the City of Fort Lauderdale, recently requested that the Coast Guard temporarily change the operating regulations for these bridges during parts of the 2003 Air and Sea Show to allow the considerable volume of vehicular and pedestrian traffic to be routed from the beach as safely and quickly as possible. These temporary changes to the bridge operating regulations will require the East Sunrise Boulevard (SR 838) and East Las Olas bridges in Fort Lauderdale, Florida to remain closed from 4 p.m. to 6 p.m. and 9:45 p.m. to 10:45 p.m. on May 3, 2003, and from 4 p.m. to 6 p.m. on May 4, 2003, except that, the East Sunrise Boulevard bridge (SR 838) may open at 4:45 p.m. and 5:30 p.m. each day, and the East Las Olas bridge may open at 4:30 p.m. and 5:15 p.m. each day on May 3 and 4, 2003. In accordance with 33 CFR 117.261 (a), public vessels of the United States, tugs with tows, and vessels in a situation where a delay would endanger life or property shall, upon proper signal, be passed through the draw of each bridge at any time.

Discussion of Rule

This temporary rule allows these bridges to remain closed for periods of time on May 3 and 4, 2003, to facilitate the vehicle traffic flow to and from the Air & Sea Show. The bridges' operating schedules will only be changed for a total of five hours over a two-day period and include two openings each day during each afternoon period affected by this temporary rule, and the longest a vessel will have to wait for an opening is one hour during the evenings of May 3, 2003, and May 4, 2003.

Regulatory Evaluation

This rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not "significant" under the

regulatory policies and procedures of the Department of Homeland Security (DHS). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The bridges' operating schedules will only be changed for five hours over a two-day period and include two openings each day during each afternoon period affected by this temporary rule, and the longest a vessel will have to wait for an opening is one hour during the evenings of May 3, 2003, and May 4, 2003.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601-612), we considered whether this temporary rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this temporary rule will not have a significant economic impact on a substantial number of small entities as the regulations will only be changed for five hours over a two-day period and include two openings each day during each afternoon period affected by this temporary rule, and the longest a vessel will have to wait for an opening is one hour during the evenings of May 3, 2003, and May 4, 2003.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this temporary rule would have a significant economic impact on it, please submit a comment (*see ADDRESSES*) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104-121), we want to assist small entities in understanding this temporary rule so that they can better evaluate its effects on them and participate in the rulemaking. If this temporary rule affects your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in **FOR FURTHER INFORMATION CONTACT**.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine

compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This temporary rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under Executive Order 13132 and have determined that this rule does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531-1538) requires Federal agencies to assess the effects of their regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector, of \$100,000,000 or more in any one year. Although this temporary rule would not result in such an expenditure, we do discuss the effects of this rule elsewhere in the preamble.

Taking of Private Property

This rule would not effect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations that Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this proposed rule under Commandant Instruction M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2-1, paragraph (32)(e), of the Instruction from further environmental documentation. Under figure 2-1, paragraph (32)(e), of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this rule.

List of Subjects in 33 CFR Part 117

Bridges.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

■ 1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170; 33 CFR 1.05-1(g); Section 117.255 also issued under the authority of Pub. L. 102-587, 106 Stat. 5039.

■ 2. From 4 p.m. on May 3, 2003 until 6 p.m. on May 4, 2003, in § 117.261, temporarily suspend paragraph (gg) and add temporary paragraphs (ss) and (tt) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(ss) East Las Olas bridge, mile 1064 at Fort Lauderdale. The draw shall open on signal except that on May 3 and 4, 2003, from 4 p.m. to 6 p.m. each day, the draw need only open at 4:30 p.m. and 5:15 p.m., and on May 3, 2003, from 9:45 p.m. to 10:45 p.m., the draw need not open.

(tt) East Sunrise Boulevard bridge (SR 838), mile 1062.6 at Fort Lauderdale. The draw shall open on signal except that on May 3 and 4, 2003, from 4 p.m. to 6 p.m. each day, the draw need only open at 4:45 p.m. and 5:30 p.m., and, on May 3, 2003, from 9:45 p.m. to 10:45 p.m., the draw need not open.

Dated: April 16, 2003.

James S. Carmichael,

*Rear Admiral, Coast Guard, Commander,
Seventh Coast Guard District.*

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[COTP San Juan-03-047]

RIN 1625-AA00

Security Zone; St. Croix, United States Virgin Islands

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; request for comments.

SUMMARY: The Coast Guard is establishing a temporary security zone in the vicinity of the HOVENSA refinery facility on St. Croix, U.S. Virgin Islands. This security zone extends three miles seaward from the HOVENSA facility waterfront area along the south coast of the island of St. Croix, U.S. Virgin Islands. All vessels must receive permission from the U.S. Coast Guard Captain of the Port San Juan prior to entering this temporary security zone. This security zone is needed for national security reasons to protect the public and the HOVENSA facility from potential subversive acts.

DATES: This regulation is effective at 6 p.m. on March 18, 2003 until 11:59 p.m. on June 15, 2003. Comments and related

material must reach the Coast Guard on or before June 27, 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 (COTP San Juan-03-047) and are available for inspection or copying at Marine Safety Office San Juan, RODVAL Bldg, San Martin St. #90 Ste 400, Guaynabo, PR 00968, between 7 a.m. and 3:30 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: LCDR Michael Roldan, Marine Safety Office San Juan, Puerto Rico at (787) 706-2440.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a NPRM. Publishing a NPRM and delaying the rule's effective date would be contrary to the public interest since immediate action is needed to protect the public, ports and waterways of the United States. The Coast Guard will issue a broadcast notice to mariners to advise mariners of the restriction.

For the same reasons, under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**.

Similar regulations were established on December 19, 2001 and published in the **Federal Register** (67 FR 2332), and on September 13, 2002 and published in the **Federal Register** (67 FR 57952). However, these regulations expired on June 15, 2002 and December 15, 2002, respectively. We did not receive any comments on these two regulations. The Captain of the Port San Juan has determined that the need to continue to have this regulation in place exists. The Coast Guard intends to publish a notice of proposed rulemaking to propose making this temporary rule a final rule.

Request for Comments

Although the Coast Guard has good cause to implement this regulation without a notice of proposed rulemaking, we want to afford the public the opportunity to participate in this rulemaking by submitting comments and related material regarding the size and boundaries of these security zones in order to minimize unnecessary burdens. If you do so, please include your name and address, identify the docket number for this rulemaking (COTP San Juan 03-