

This oxytetracycline/neomycin use combination is listed in the table in § 558.15(g)(2) and is the only use combination listed in this provision. Because this use combination's approval is now reflected in § 558.455, FDA is removing § 558.15(g)(2) as obsolete or redundant. As in the 2006 final rule, FDA is retaining the sole listing in the table in § 558.15(g)(1) for NADA 141-137 as well as § 558.15(a) through (f), and intends to continue to finalize the proposed rule to remove all of § 558.15.

II. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

III. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601-602), and the Unfunded Mandates Reform Act of 1995 (Public Law 104-4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is not a significant regulatory action under the Executive order.

FDA proposed the removal of § 558.15 on August 8, 2003, because it was obsolete or redundant. The original purpose of § 558.15, requiring the submission of the results of studies on the long-term administration of then-marketed antimicrobial drugs in animal feed on the occurrence of multiple drug-resistant bacteria associated with these animals, was obsolete as FDA had a new strategy and concept for assessing the safety of antimicrobial new animal drugs, including subtherapeutic use of antimicrobials in animal feed, with regard to their microbiological effects on bacteria of human health concern. This final rule would delete the only animal drug use combination listed in § 558.15(g)(2) which is redundant because its approved conditions of use are now listed in § 558.455.

A. Benefits

Only one set of comments on the proposal was received by FDA. Because these comments did not question the

benefits as described in the proposed rule, we retain the benefits for the final rule. This final rule is expected to provide greater clarity in the regulations for new animal drugs for use in animal feeds by deleting obsolete provisions in § 558.15. We do not expect this final rule to result in any direct human or animal health benefit. Rather, this final rule would remove regulations that are no longer necessary.

B. Compliance Costs

We do not expect the final rule that revokes § 558.15(g)(2) to have a substantive effect on any approved new animal drugs, or to cause any approved new animal drug to lose its marketing ability or experience a loss of sales.

C. Regulatory Flexibility Analysis

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. FDA has determined that this final rule does not impose compliance costs on the sponsors of any products that are currently marketed. Further, it does not cause any drugs that are currently marketed to lose their marketing ability. We therefore certify that this final rule would not have a significant economic effect on a substantial number of small entities.

D. Unfunded Mandates Reform Act

Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement, which includes an assessment of anticipated costs and benefits, before proposing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is \$133 million, using the most current (2008) Implicit Price Deflator for the Gross Domestic Product. FDA does not expect this final rule to result in any 1-year expenditure that would meet or exceed this amount.

IV. Paperwork Reduction Act of 1995

FDA concludes that this rule does not have information collection requirements.

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, 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.

§ 558.15 [Amended]

■ 2. In § 558.15, remove and reserve paragraph (g)(2).

Dated: March 18, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-7108 Filed 3-30-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2009-0959]

RIN 1625-AA09

Drawbridge Operation Regulation; Chehalis River, Aberdeen, WA, Schedule Change

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: The Coast Guard is changing the regulations that govern the operation of the U.S. Highway 101 bascule bridge across the Chehalis River, mile 0.1, at Aberdeen, Washington. At least one-hour notice by telephone will be required at all times for draw openings. The change is necessary to allow the bridge owner to reduce the staffing requirements of the bridge in light of the infrequent openings requested for the bridge.

DATES: This rule is effective April 30, 2010.

ADDRESSES: Comments and related materials received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG-2009-0959 and are available online by going to <http://www.regulations.gov>, inserting USCG-2009-0959 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying at the Docket Management Facility (M-60), U.S. Department of Transportation, West Building, Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or

e-mail Austin Pratt, Chief, Bridge Section, Waterways Management Branch, 13th Coast Guard District; telephone 206–220–7282, e-mail william.a.pratt@uscg.mil. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On December 4, 2009, we published a notice of proposed rulemaking (NPRM) entitled Drawbridge Operation Regulations; Chehalis River, Aberdeen, WA, Schedule Change in the **Federal Register** (74 FR 63695). We received no comments on the proposed rule. No public meeting was requested and none was held.

Background and Purpose

This rule enables the Washington State Department of Transportation, the owner of the Chehalis River Bridge, to operate the draw only if at least one-hour notice is provided at all times. This notice will be given by telephone to 360–533–9360. A marine radio will also be maintained at the bridge, but will only be monitored when a draw tender is present. Previously, one-hour notice was only required between 9 p.m. and 5 a.m.

Over the years ship traffic has dwindled on this reach of the Chehalis River. From June through September 2009 the draw did not open for large oceangoing vessels. The former ship traffic is now focused seaward of the bridge following the recent closure of timber terminals above the bridge. The bridge averages only seven openings a month during those daylight hours when a draw operator is present. The Washington State Department of Transportation requested this change to reduce unnecessary staffing of the drawbridge in light of the infrequent openings requested for the bridge.

Discussion of Comments and Changes

No comments were received on the proposed rule and no changes were made to the proposed rule.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Regulatory Planning and Review

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. The Coast Guard has made this determination based on the fact that vessel operators will not be significantly impacted since they will still be able to transit under the bridge by giving one-hour notice.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this 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 rule would not have a significant economic impact on a substantial number of small entities because all vessel operators will not be significantly impacted since they will still be able to transit under the bridge by giving one-hour notice.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding this rule so that they can better evaluate its effects on them and participate in the rulemaking process.

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). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This 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 that Order and have determined that it 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 discretionary 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. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not affect 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 would not create an environmental risk to health or risk to safety that might 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. The Administrator of Information and Regulatory Affairs has not designated this as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01, and Commandant Instruction M16475.ID, 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 this action is one of a category of actions which do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (32)(e), of the Instruction.

Under figure 2-1, paragraph (32)(e), of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required.

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; 33 CFR 1.05-1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Revise § 117.1031 to read as follows:

§ 117.1031 Chehalis River.

The draw of the U.S. 101 highway bridge, mile 0.1, at Aberdeen shall open on signal if at least one-hour notice is given at all times by telephone to the Washington State Department of Transportation.

Dated: March 11, 2010.

G.T. Blore,

Rear Admiral, U.S. Coast Guard, Commander, Thirteenth Coast Guard District.

[FR Doc. 2010-7166 Filed 3-30-10; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG-2010-0185]

Drawbridge Operation Regulation; Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, Chesapeake, VA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Fifth Coast Guard District, has issued a temporary deviation from the regulations governing the operation of the SR170 Centerville Turnpike Bridge across the Atlantic Intracoastal Waterway, Albemarle and Chesapeake Canal, mile 15.7, at Chesapeake, VA. The deviation is necessary to facilitate structural repairs to the swing span. This deviation allows the drawbridge to remain in the closed to navigation position.

DATES: This deviation is effective from 8 a.m. on April 10, 2010 to 6 p.m. on April 18, 2010.

ADDRESSES: Documents mentioned in this preamble as being available in the docket USCG-2010-0185 and are available online by going to <http://www.regulations.gov>, inserting USCG-2010-0185 in the "Keyword" box, and then clicking "Search". This material is also available for inspection or copying the Docket Management Facility (M-30),

U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or e-mail Mr. Bill H. Brazier, Bridge Management Specialist, Fifth Coast Guard District; telephone (757) 398-6422, e-mail Bill.H.Brazier@uscg.mil. If you have questions on reviewing the docket, call Renee V. Wright, Program Manager, Docket Operations, (202) 366-9826.

SUPPLEMENTARY INFORMATION: The City of Chesapeake, who owns and operates this swing-type bridge, has requested a temporary deviation from the current operating regulations set out in 33 CFR 117.997(i), to facilitate structural repairs.

The SR170 Centerville Turnpike Bridge has a vertical clearance in the closed position to vessels of four feet above mean high water.

Under this temporary deviation, the drawbridge will be maintained in the closed to navigation position to facilitate repairs to structural support stringers on two separate closures. The first closure period will begin at 8 a.m. April 10, 2010, until and including 6 p.m. April 11, 2010; and the second closure period scheduled to begin at 8 a.m. on April 17, 2010, until and including 6 p.m. on April 18, 2010. Openings will be provided during the closure periods at the following times: on Saturdays at 8 a.m., 10 a.m., noon, 2 p.m., 4 p.m., 6 p.m., 8 p.m., and 10 p.m., and on Sundays at midnight, 2 a.m., 4 a.m., 6 a.m., 8 a.m., 10 a.m., noon, 2 p.m., 4 p.m., and 6 p.m.

The Atlantic Intracoastal Waterway caters to a variety of vessels from tug and barge traffic to recreational vessels traveling from Florida to Maine. The Coast Guard has carefully coordinated the restrictions with commercial and recreational waterway users. Additionally, the Coast Guard will inform unexpected users of the waterway through our local and broadcast Notices to Mariners of the closure periods for the bridge so that vessels can arrange their transits to minimize any impacts caused by the temporary deviation. The Atlantic Ocean is the alternate route for vessels and the bridge will be able to open in the event of an emergency.

In accordance with 33 CFR 117.35(e), the draw must return to its original operating schedule immediately at the end of the designated time period. This