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Dated: December 16, 2004.

Steven D. Vaughn,*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 04-28578 Filed 12-29-04; 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; Tilimicosin****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 Elanco Animal Health which provides for revised reproductive safety labeling of tilimicosin Type A medicated article used in medicated swine feeds.

DATES: This rule is effective December 30, 2004.

FOR FURTHER INFORMATION CONTACT: Joan C. Gotthardt, Center for Veterinary Medicine (HFV-130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7571, e-mail: joan.gotthardt@fda.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 141-064 that provides for the use of PULMOTIL 90 (tilimicosin phosphate) Type A medicated article in swine feed for the control of swine respiratory disease associated with certain bacterial organisms. The supplemental NADA provides for revised reproductive safety labeling. The supplemental NADA is approved as of November 24, 2004, and 21 CFR 558.618 is amended 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 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.

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 qualifies for 3 years of marketing exclusivity beginning November 24, 2004.

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

§ 558.618 [Amended]

■ 2. Section 558.618 is amended in paragraph (e)(3) in the third sentence by removing "pregnant swine or" and by adding in its place "male".

Dated: December 20, 2004.

Steven D. Vaughn,*Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.*

[FR Doc. 04-28576 Filed 12-29-04; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117****[CGD01-04-148]****Drawbridge Operation Regulations: Newtown Creek, Dutch Kills, English Kills, and Their Tributaries, NY****AGENCY:** Coast Guard, DHS.**ACTION:** Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Metropolitan Avenue Bridge, mile 3.4, across English Kills at New York City, New York. Under this temporary deviation the bridge may remain closed 6 a.m. to midnight from December 27, 2004 through December 29, 2004 and January 3, 2005 through January 5, 2005. This temporary deviation is necessary to facilitate bridge maintenance.

DATES: This deviation is effective from December 27, 2004 through January 5, 2005.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668-7195.

SUPPLEMENTARY INFORMATION: The Metropolitan Avenue Bridge has a vertical clearance in the closed position of 10 feet at mean high water and 15 feet at mean low water. The existing drawbridge operation regulations are listed at 33 CFR 117.801(e).

The owner of the bridge, New York City Department of Transportation (NYCDOT), requested a temporary deviation from the drawbridge operation regulations to facilitate rehabilitation repairs at the bridge. The bridge must remain in the closed position to perform these repairs.

Under this temporary deviation the NYCDOT Metropolitan Avenue Bridge may remain in the closed position 6 a.m. through midnight from December 27, 2004 through December 29, 2004 and January 3, 2005 through January 5, 2005.

This deviation from the operating regulations is authorized under 33 CFR 117.35, and will be performed with all due speed in order to return the bridge to normal operation as soon as possible.

Dated: December 20, 2004.

David P. Pekoske,*Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.*

[FR Doc. 04-28547 Filed 12-29-04; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY**Coast Guard****33 CFR Part 117****[CGD01-04-151]****Drawbridge Operation Regulations: Connecticut River, CT****AGENCY:** Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, First Coast Guard District, has issued a temporary deviation from the drawbridge operation regulations for the Amtrak Old Saybrook-Old Lyme Bridge, mile 3.4, across the Connecticut River, Connecticut. Under this temporary deviation, effective from February 21, 2005 through March 31, 2005, the bridge shall open on signal on a fixed schedule at 8 a.m., 12 p.m., 4 p.m., and 8 p.m. From 8 p.m. to 8 a.m. the draw shall open on signal after at least a four-hour advance notice is given. This deviation is necessary in order to facilitate necessary repairs at the bridge.

DATES: This deviation is effective from February 21, 2005 through March 31, 2005.

FOR FURTHER INFORMATION CONTACT: Judy Leung-Yee, Project Officer, First Coast Guard District, at (212) 668-7195.

SUPPLEMENTARY INFORMATION: The Old Saybrook-Old Lyme Bridge, at mile 3.4 across the Connecticut River has a vertical clearance in the closed position of 19 feet at mean high water and 22 feet at mean low water. The existing drawbridge operating regulations are listed at 33 CFR 117.205(b).

The owner of the bridge, Amtrak, requested a temporary deviation from the drawbridge operating regulations to facilitate structural repairs at the bridge.

This deviation to the operating regulations allows the Old Saybrook-Old Lyme Bridge to operate on a fixed opening schedule from February 21, 2005 through March 31, 2005. The bridge shall open only at 8 a.m., 12 p.m., 4 p.m., and 8 p.m. and from 8 p.m. through 8 a.m., the draw shall open on signal after at least a four-hour advance notice is given.

In accordance with 33 CFR 117.35(c), this work will be performed with all due speed in order to return the bridge to normal operation as soon as possible. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: December 14, 2004.

John L. Grenier,

*Captain, U.S. Coast Guard, Acting
Commander, First Coast Guard District.*

[FR Doc. 04-28553 Filed 12-29-04; 8:45 am]

BILLING CODE 4910-15-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD01-04-152]

RIN 1625-AA11

Regulated Navigation Area; East Rockaway Inlet to Atlantic Beach Bridge, Nassau County, Long Island, NY

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule with request for comments.

SUMMARY: The Coast Guard is re-establishing a temporary regulated navigation area (RNA) that was in effect from 6 December to 10 December, until 10 March 2005. The area of this RNA covers the entrance of East Rockaway Inlet to the Atlantic Beach Bridge, Nassau County, New York. This rule restricts the passage of commercial vessels carrying petroleum products with a loaded draft in excess of five feet. Significant shoaling in this area has reduced the depths of the navigable channel making the area unsafe for passage of vessels with drafts of greater than five feet carrying petroleum products as cargo. Operators of such vessels may request transit of the area on a trip-by-trip basis to the Captain of the Port, Long Island Sound, New Haven, Connecticut.

DATES: This rule is effective from 12:01 a.m. on December 11, 2004 until 11:59 p.m. on March 10, 2005. Comments must be received on or before January 10, 2005.

ADDRESSES: Comments should be mailed to the Waterways Management Officer, Coast Guard Group/Marine Safety Office Long Island Sound, 120 Woodward Ave., New Haven, CT 06512. Comments received, along with documents indicated in this preamble as being available in the docket, are part of docket CGD01-04-152 and will be available for inspection or copying at Group/MSO Long Island Sound, New Haven, CT, at the address above, between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant A. Logman, Waterways Management Officer, Coast Guard Group/Marine Safety Office Long Island Sound at (203) 468-4429.

SUPPLEMENTARY INFORMATION:

Request for Comments and Public Meeting

Interested persons are invited to participate in this rulemaking by submitting written views, comments, data, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD01-04-152), the specific section of this rule to which each comment applies, and give reasons for each comment. The Coast Guard requests that all comments and attachments be submitted in an 8½" x 11" unbound format suitable for copying and electronic filing. If that is not practical, a second copy of any bound material is requested. Persons desiring acknowledgment that their comments have been received should enclose a stamped, self-addressed post card or envelope.

The Coast Guard will consider all comments received during the comment period, and may modify this temporary final rule in light of comments received. The Coast Guard plans no public hearing. Persons may request a public hearing by writing to Waterways Management Officer, Group/Marine Safety Office Long Island Sound at the address listed under **ADDRESSES** above. The request should include reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

In accordance with 5 U.S.C. 553(d)(3) good cause exists for publishing a temporary final rule without a prior comment period. Due to the immediate need for the protection of the maritime public, it is impracticable to publish a NPRM in advance. Delaying this rule to provide for a notice and comment period would be impracticable, unnecessary and contrary to the public interest. Any delay in implementing this rule would be contrary to public interest as immediate action is needed to prevent vessels, carrying petroleum products as cargo with a loaded draft of greater than five feet, from transiting the area so as to avoid the potential hazards associated with a grounding of a vessel carrying petroleum products as cargo.

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(3)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. Due to the immediate need for the protection of the maritime public, it is impracticable to publish a NPRM in