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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]

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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; 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.*

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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.*

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