(d)(1) and by adding new paragraph (d)(2) to read as follows:

§ 173.325 Acidified sodium chlorite solutions.

* * * * *

(d)(1) * * *

(2) The additive is used as a single application in processing facilities as an antimicrobial agent to reduce pathogenic bacteria due to cross-contamination during the harvesting, handling, heading, evisceration, butchering, storing, holding, packing, or packaging of finfish and crustaceans; or following the filleting of finfish; in accordance with current industry standards of good manufacturing practice. Applied as a dip or spray, the additive is used at levels that result in a sodium chlorite concentration of 1,200 ppm, in combination with any GRAS acid at levels sufficient to achieve a pH of 2.3 to 2.9. Treated seafood shall be cooked prior to consumption.

* * * * *

Dated: December 21, 2004.

Leslye M. Fraser,

Director, Office of Regulations and Policy, Center for Food Safety and Applied Nutrition.

[FR Doc. 04–28577 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; Chlortetracycline

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to add the approved withdrawal time to the limitations to conditions of use for chlortetracycline Type C medicated feeds for chickens when fed at the 500 gram per ton level. This change is being made to improve the accuracy of the regulations.

DATES: This rule is effective December 30, 2004.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV– 6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–4567, e-mail: *george.haibel@fda.gov.*

SUPPLEMENTARY INFORMATION: FDA has found that the April 1, 2004, edition of Title 21, Parts 500 to 599 of the Code of Federal Regulations (CFR) does not reflect the approved withdrawal time for chlortetracycline in Type C medicated feeds for chickens when fed at the 500 gram per ton level. The approved 24-hour withdrawal time at this dose level was inadvertently removed for all sponsors at the time of a supplemental approval of a zero-day withdrawal time for AUREOMYCIN Type C medicated chicken feeds under NADA 48–761 (63 FR 57245 at 57247, October 27, 1998). At this time, FDA is amending the regulations to correct this error in 21 CFR 558.128. This action is being taken to improve the accuracy of the regulations.

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.

■ 2. Section 558.128 is amended by revising paragraph (e)(1)(iv) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(e) * * *

(1) * * *

Chlortetracycline amount	Indications for use	Limitations	Sponsor
*	*	*	*
(iv) 500 g/ton	Chickens: For the reduction of mortality due to *E. coli* infections susceptible to chlortetracycline.	1. Feed for 5 d; 0-day withdrawal time when formulated from AUREOMYCIN Type A medicated articles or Type B medicated feeds under NADA 48–761. 2. Feed for 5 d; withdraw 24 h prior to slaughter; do not feed to chickens producing eggs for human consumption.	046573 017519, 046573, 048164, 066104
*	*	*	*

* * * * *

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; Tilmicosin

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 tilmicosin 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 (tilmicosin 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]

BILLING CODE 4160–01–S

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.