

Drug labeler code	Firm name and address
012799	Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059.

Dated: July 7, 1997.

**Robert C. Livingston,**  
*Director, Office of New Animal Drug  
 Evaluation, Center for Veterinary Medicine.*  
 [FR Doc. 97-19243 Filed 7-22-97; 8:45 am]  
 BILLING CODE 4160-01-F

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 520

#### Oral Dosage Form New Animal Drugs; Tylosin

**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, Division of Eli Lilly and Co. The supplemental NADA provides for use of tylosin to make a medicated drinking water for chickens, turkeys, and swine for control and/or treatment of infections sensitive to tylosin.

**EFFECTIVE DATE:** July 23, 1997.

**FOR FURTHER INFORMATION CONTACT:** Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 13-076 that provides for use of packages containing the equivalent of 100 grams (g) of tylosin to make 50 gallons of chicken and turkey drinking water, and one-half package or 50 g of tylosin to make 200 gallons of swine drinking water, to treat tylosin sensitive infections. The tylosin base soluble powder approved under NADA 13-029 for swine and the tylosin tartrate soluble powder approved under NADA 13-076 for chickens and turkeys are considered to be DESI-equivalent based on the findings of the National Academy of Sciences/National Research

Council (NAS/NRC) review of the products and FDA's conclusions based on that review, and should have been DESI-finalized as one application. The supplement provides for incorporating NADA 13-029 into NADA 13-076 and in a separate action, withdrawing approval of NADA 13-029. The supplemental NADA is approved as of May 27, 1997, and the regulations are amended in 21 CFR 520.2640 to reflect the approval.

Approval of this supplement is an administrative action that did not require submission of added safety or efficacy data. Accordingly, a freedom of information summary is not required.

FDA has determined under 21 CFR 25.24(d)(1)(i) 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.

#### List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

#### PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

**Authority:** Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

#### § 520.2640 [Amended]

2. Section 520.2640 *Tylosin* is amended in paragraphs (e)(1)(iii) and (e)(2)(iii) by removing the phrase "as tylosin tartrate", and in paragraph (e)(3)(iii) by removing the phrase "present as tylosin base".

Dated: July 7, 1997.

**Robert C. Livingston,**  
*Director, Office of New Animal Drug  
 Evaluation, Center for Veterinary Medicine.*  
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## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 100

[CGD13-97-016]

RIN 2115-AE46

#### Special Local Regulations; Seattle Seafair Unlimited Hydroplane Race, Lake Washington, Seattle, WA

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** This final rule temporarily amends the effective date of the special local regulations for the Seattle Seafair Unlimited Hydroplane Race, to be held from August 7, 1997 to August 10, 1997. This change is needed because this year's race will occur a week later than it is normally held. These special local regulations are needed to provide for the safety of participants and spectators on the navigable waters during this event. The effect will be to restrict general navigation in the regulated area for the safety of participants and spectators of the Hydroplane Race.

**DATES:** This final rule is effective from August 7 until August 11, 1997.

**ADDRESSES:** Unless otherwise indicated, documents referred to in this preamble are available for inspection or copying at U.S. Coast Guard Marine Safety Office Puget Sound, 1519 Alaskan Way South, Building 1, Seattle, Washington 98134-1192. Normal office hours are between 7 a.m. and 5 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LT Joel Roberts, c/o Captain of the Port Puget Sound, 1519 Alaskan Way South, Seattle, Washington 98134-1192, (206) 217-6232.

#### SUPPLEMENTARY INFORMATION:

##### Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking has not been published for this regulation and good cause exists for making it effective less than 30 days from the date of publication in the **Federal Register**. Publishing a NPRM would be contrary to the public interest since immediate action is necessary to ensure the safety

of vessels and spectators on the navigable waters during this event. If normal notice and comment procedures were followed, this rule would not become effective until after the date of the event. For this reason, following normal rulemaking procedures in this case would be impracticable and contrary to the public interest.

#### Background and Purpose

This final rule temporarily amends the effective date of the special local regulations for the Seattle Seafair Unlimited Hydroplane Race contained in 33 CFR 100.1301. This year's races will be held between August 7, 1997 and August 10, 1997. This change is needed because this year's race will occur a week later than it is normally held. These special local regulations are needed to provide for the safety of participants and spectators on the navigable waters during this event. The effect will be to restrict general navigation in the regulated area for the safety of participants and spectators of the Hydroplane Race.

The Seattle Seafair Unlimited Hydroplane Race occurs annually on the waters of Lake Washington. Participant craft are high speed, high performance vessels which can be restricted in their ability to maneuver within a short distance. The competition consistently draws large numbers of spectator craft. The implementation of the special local regulations on the dates specified in temporary section 33 CFR 100.1301 enhance the safety of the participants and spectators.

#### Regulatory Evaluation

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that order. It has been exempted from review by the Office of Management and Budget under that order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT) (44 CFR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal, due to the event's short duration, that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary.

#### Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. "Small entities" include independently

owned and operated small businesses that are not dominant in their field and that otherwise qualify as "small business concerns" under section 3 of the Small Business Act (15 U.S.C. 632). Because the impacts of this rule are expected to be minimal, due to the event's short duration, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601–612) that this rule will not have a significant economic impact on a substantial number of small entities.

#### Collection of Information

This rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501–3520).

#### Federalism

The Coast Guard has analyzed this final rule in accordance with the principles and criteria contained in Executive Order 12612 and has determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

#### Environment

The Coast Guard has considered the environmental impact of this rule and has concluded that under Section 2.B.2.e of Commandant Instruction M16475.1B, it is categorically excluded from further environmental documentation.

#### List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

#### Final Regulation

For the reasons set out in the preamble, the Coast Guard amends part 100 of Title 33, Code of Federal Regulations, as follows:

#### PART 100—[AMENDED]

1. The authority citation for part 100 continues to read as follows:

**Authority:** 33 U.S.C. 1233; 49 CFR 1.46.

2. From August 7 until August 11, 1997, in § 100.1301, paragraph (a) is suspended and a new paragraph (j) is added to read as follows:

#### § 100.1301 [Amended]

\* \* \* \* \*

(j) This regulation is in effect from August 7–11, 1997.

Dated: July 14, 1997.

**E.I. Kiley,**

*Captain, U.S. Coast Guard, Acting District Commander, Thirteenth Coast Guard District.*  
[FR Doc. 97–19408 Filed 7–22–97; 8:45 am]

BILLING CODE 4910–14–M

## DEPARTMENT OF TRANSPORTATION

### Coast Guard

#### 33 CFR Part 165

[CGD13–97–015]

#### Safety Zone Regulation; Elliott Bay, Seattle, WA

**AGENCY:** Coast Guard, DOT.

**ACTION:** Final rule.

**SUMMARY:** The Coast Guard is amending 33 CFR 165.1307 to correct an error in the description of the safety zone. On the 4th of July each year a fireworks display is launched from a barge positioned upon the waters of Elliott Bay, Seattle, WA. A safety zone is established around the barge to promote the safety of spectators and participants during this event.

**EFFECTIVE DATE:** July 23, 1997.

**ADDRESSES:** Unless otherwise indicated, documents referred to in this preamble are available for inspection and copying at U.S. Coast Guard Marine Safety Office Puget Sound, 1519 Alaskan Way South, Building 1, Seattle, Washington 98134. Normal office hours are between 7 a.m. and 5 p.m., Monday through Friday, except federal holidays.

**FOR FURTHER INFORMATION CONTACT:** LT Joel Roberts, c/o Captain of the Port Puget Sound, 1519 Alaskan Way South, Seattle, Washington 98134, (206) 217–6232.

#### SUPPLEMENTARY INFORMATION:

#### Background and Purpose

The Coast Guard is amending 33 CFR 165.1307 to correct an error in the description of the safety zone. The safety zone was intended to resemble a square centered around the barge from which the fireworks will be launched. The position describing the western corner of the safety zone contained incorrect digits in the latitude and longitude.

This error displaced the western corner of the safety zone one mile from its intended position. That position is corrected along with an additional minor refinement to the description of the eastern corner point of the safety zone to better establish the originally intended square.