Substances	Limitations
* * *	* * * *
Oxidized bis (hydrogenated tallow alkyl) amines	For use only: 1. At levels not to exceed 0.1 percent by weight of polypropylene polymers complying with § 177.1520(c) of this chapter, item 1.1, 1.2, 1.3, 3.1a (density not less than 0.85 gram per cubic centimeter and less than 0.91 gram per cubic centimeter), 3.2b, 3.4, and 3.5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter and with food types III, IV–A, V, VI, VII–A, and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter. 2. At levels not to exceed 0.075 percent by weight of high-density polyethylene polymers complying with § 177.1520(c) of this chapter, item 2.1, 2.2, 2.3, 3.1a, 3.1b, 3.2a, 3.6 (density not less than 0.94 gram per cubic centimeter), and 5. The finished polymers may be used in contact with food types I, II, IV–B, VII–B and VIII described in Table 1 of § 176.170(c) of this chapter, under conditions of use B through H described in Table 2 of § 176.170(c) of this chapter, and with food types III, IV–A, V, VI, VII–A and IX described in Table 1 of § 176.170(c) of this chapter, under conditions of use D through H described in Table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: July 3, 1997.

Janice F. Oliver,

Deputy Director for Systems and Support, Center for Food Safety and Applied Nutrition.

[FR Doc. 97–19250 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 510

New Animal Drugs; Change of Sponsor Address

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor address for Hoechst Roussel Vet.

EFFECTIVE DATE: July 23, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Rt. 202–206, P.O. Box 2500, Somerville, NJ 08876–1258, has informed FDA of a change of sponsor address to Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

List of Subjects in 21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

2. Section 510.600 is amended in the table in paragraph (c)(1) by revising the entry for ''Hoechst Roussel Vet'' and in the table in paragraph (c)(2) in the entry for ''012799'' by revising the sponsor address to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

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

(2) * * *

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.

[FR Doc. 97–19245 Filed 7–22–97; 8:45 am]

BILLING CODE 4160–01–F

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