

of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objection received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 177

Food additives, Food packaging.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 177 is amended as follows:

PART 177—INDIRECT FOOD ADDITIVES: POLYMERS

1. The authority citation for 21 CFR part 177 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 177.1520 is amended in the table in paragraph (c) by revising item "6." under the heading "Density" to read as follows:

§ 177.1520 Olefin polymers.

* * * * *

(c) * * *

Olefin polymers	Density	Melting Point (MP) or softening point (SP) (Degrees Centigrade)	Maximum extractable fraction (expressed as percent by weight of the polymer) in <i>N</i> -hexane at specified temperatures	Maximum soluble fraction (expressed as percent by weight of polymer) in xylene at specified temperatures
6. Ethylene-maleic anhydride copolymers described in paragraph (a)(6) of this section for use as the adhesive component in multilaminar structures, or as the sealant layer in flexible packaging, in contact with food at temperatures not exceeding 49 °C (120 °F)	0.92 or greater	* * *	1.36 pct at 50 °C.	2.28 pct at 25 °C

* * * * *

Dated: May 5, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-12962 Filed 5-21-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Selenium, Vitamin E Injection

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 previously approved supplemental new animal drug application (NADA) held by Schering-Plough Animal Health Corp. and to remove certain information no longer required in the regulations. The approval concerns use of selenium, vitamin E injection.

EFFECTIVE DATE: May 24, 1999.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug

Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., P.O. Box 1982, Union, NJ 07083-1982, provided information to support prior approval of supplemental NADA 30-315 for selenium, vitamin E injection. The supplement for use of 2 percent benzyl alcohol instead of 1:10,000 thimerosal had been approved by letter of August 10, 1981. FDA reviewed the information and concurred that the change in ingredient was approved. FDA also reviewed the information requirements of the animal drug regulations and determined that specification of ingredients other than active ingredients is not needed. Therefore, 21 CFR 522.2100 is amended to remove statement of ingredients other than active ingredients.

List of Subjects in 21 CFR Part 522

Animal drugs.

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 522.2100 [Amended]

2. Section 522.2100 *Selenium, vitamin E injection* is amended in paragraph (a)(1) by removing ", 250 milligrams polyoxyethylated vegetable oil, and 2.0 percent benzyl alcohol, and water for injection"; in paragraph (b)(1) by removing ", 100 milligrams of polyoxyethylated vegetable oil, 1:10,000 thimerosal, and water for injection"; and in paragraphs (c)(1), (d)(1), and (e)(1) by removing ", 250 milligrams polysorbate 80, 2 percent benzyl alcohol, water for injection q.s".

Dated: May 11, 1999.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 99-12963 Filed 5-21-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-99-038]

RIN 2115-AA97

Safety Zone: Unity Electric Co. Fireworks Display, Shinnecock Bay, Hampton Bays, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for the Unity Electric Company Fireworks Display to be held on the waters surrounding Jackson's Marina on Shinnecock Bay, Hampton Bays, NY, on June 19, 1999. This action is needed to protect persons, facilities, vessels, and others in the maritime community from the hazards associated with this fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation is effective on June 19, 1999, from 9:00 p.m. until 10:00 p.m.

ADDRESSES: Documents relating to this temporary final rule are available for inspection and copying at U.S. Coast Guard Group Long Island Sound, 120 Woodward Avenue, New Haven, CT 06512. Normal office hours are between 8:00 a.m. and 4:00 p.m., Monday through Friday, except holidays. Comments may also be faxed to this address. The fax number is (203) 468-4445.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander T. J. Walker, Chief of Port Operations, Captain of the Port, Long Island Sound, at (203) 468-4444.

SUPPLEMENTARY INFORMATION:**Regulatory History**

Pursuant to 5 U.S.C. 553, good cause exists for not publishing a notice of proposed rulemaking (NPRM) and for making this rule effective in less than 30 days after publication in the **Federal Register**. The sponsor of the event did not provide the Coast Guard with the final details for the event in sufficient time to publish a NPRM or a final rule 30 days in advance. The delay encountered if normal rulemaking procedures were followed would effectively cancel the event. Cancellation of this event is contrary to the public interest since the fireworks display is for the benefit of the public.

Background and Purpose

The Unity Electric Company is sponsoring a 15-minute fireworks display on the waters off of Shinnecock Bay, Hampton Bays, New York. The fireworks display will occur on June 19, 1999, from 9:30 pm until 9:45 pm. The safety zone covers all waters of Shinnecock Bay within a 1000-foot radius of the fireworks-launching site, which will be located in Jackson's Marina in Hampton Bays in approximate position 40°57'.00 N, 073°04.17 W (NAD 1983). This zone is

to protect the maritime community from the hazards associated with this fireworks display. Entry into or movement within this zone will be prohibited unless authorized by the Captain of the Port or his on-scene representative.

Regulatory Evaluation

This temporary final 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 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This safety zone involves only a portion of Shinnecock Bay, and entry into this zone will be restricted for only 60 minutes, on June 19, 1999, from 9:00 p.m. to 10:00 p.m. Although this regulation prevents traffic from transiting from and to Jackson's Marina, the effect of this regulation will not be significant for several reasons: The duration of the event is limited; the event is at a late hour; and extensive, advance maritime advisories will be made.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this temporary final rule would 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 (2) governmental jurisdictions with populations of less than 50,000.

For the reasons discussed under the Regulatory Evaluation above, the Coast Guard certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this rule will not have a significant impact on a substantial number of small entities.

Assistance for Small Entities

Under subsection 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 [Pub. L. 104-121], the Coast Guard wants to assist small entities in understanding this temporary final rule so that they can better evaluate its effects on them and participate in the rulemaking. If your

small business or organization would be affected by this rule and you have questions concerning its provisions or options for compliance, please call LCDR T.J. Walker, telephone (203) 468-4444.

The Ombudsman of Regulatory Enforcement for Small Business and Agriculture, and 10 Regional Fairness Boards, were established to receive comments from small businesses about enforcement by Federal agencies. The Ombudsman will annually evaluate such enforcement and rate each agency's responsiveness to small business. If you wish to comment on enforcement by the Coast Guard, call 1-888-REG-FAIR (1-888-734-3247).

Collection of Information

This temporary final rule contains no collection-of-information requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*).

Federalism

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

Unfunded Mandates

Under the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), the Coast Guard must consider whether this temporary final rule will result in an annual expenditure by State, local, and tribal governments, in aggregate, of \$100 million (adjusted annually for inflation). If so, the Act requires that a reasonable number of regulatory alternatives be considered, and that, from those alternatives, the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule be selected. No State, local, or tribal governments will be affected by this rule, so this rule will not result in annual or aggregate costs of \$100 million or more. Therefore, the Coast Guard is exempt from any further regulatory requirements under the Unfunded Mandates Act.

Environment

The Coast Guard has considered the environmental impact of this temporary final rule and concluded that under Figure 2-1, paragraph 34(g), of Commandant Instruction, M 16475.C, this rule is categorically excluded from further environmental documentation. A written Categorical Exclusion Determination is available in the docket

for inspection or copying where indicated under **ADDRESSES**.

Other Executive Orders on the Regulatory Process

In addition to the statutes and Executive Orders already addressed in this preamble, the Coast Guard considered the following executive orders in developing this temporary final rule and reached the following conclusions:

E.O. 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights. This final rule will not effect a taking of private property or otherwise have taking of private property or otherwise have taking implications under this Order.

E.O. 12875, Enhancing the Intergovernmental Partnership. This final rule meets applicable standards in sections 3(a) and 3(b)(2) of this Order to minimize litigation, eliminate ambiguity, and reduce burden.

E.O. 13405, Protection of Children from Environmental Health Risks and Safety Risks. This final rule is not an economically significant rule and does not concern an environmental risk to safety disproportionately affecting children.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reports and recordkeeping requirements, Security measures, Waterways.

Regulation

For the reasons set out in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—[AMENDED]

1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46. Section 165.100 is also issued under authority of Sec. 311, Pub. L. 105–383.

2. Add temporary § 165.T01–CGD1–038 to read as follows:

§ 165.T01–CGD1–038 Unity Electric Co. Fireworks Display, Shinnecock Bay, Hampton Bays, NY.

(a) *Location.* The safety zone includes all waters of Shinnecock Bay within a 1000-foot radius of the launch site located in Jackson's Marina in approximate position 40°57'.00 N, 073°04'.17 W (NAD 1983).

(b) *Effective date.* This section is effective on June 19, 1999, from 9:00 p.m. until 10:00 p.m.

(c) *Regulations.* (1) The general regulations covering safety zones contained in § 165.23 apply.

(2) All persons and vessels shall comply with the instructions of the Coast Guard Captain of the Port or the designated on-scene patrol personnel. Among these personnel are commissioned, warrant, and petty officers of the Coast Guard. Upon being hailed by a U.S. Coast Guard Vessel by siren, radio, flashing light, or other means, the operator of a vessel shall proceed as directed.

P.K. Mitchell,

Captain, Coast Guard, Captain of the Port, Long Island Sound.

[FR Doc. 99–12955 Filed 5–21–99; 8:45 am]

BILLING CODE 4910–15–M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–99–040]

RIN 2115–AA97

Safety Zone: 4th of July Celebration Fireworks Display, Great South Bay, Sayville, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for the Lesbian & Gay Community Services Center Fireworks Display to be held at Great South Bay, Sayville, NY, on July 3, 1999. This safety zone is needed to protect persons, facilities, vessels, and others in the maritime community from the hazards associated with this fireworks display. Entry into this safety zone is prohibited unless authorized by the Captain of the Port.

EFFECTIVE DATE: This regulation is effective on July 3, 1999, from 9:30 p.m. until 10:35 p.m. For rain date, refer to the regulatory text set out in this rule.

ADDRESSES: Documents relating to this temporary final rule are available for inspection and copying at U.S. Coast Guard Group Long Island Sound, 120 Woodward Avenue, New Haven, CT 06512. Normal office hours are between 8:00 a.m. and 4:00 p.m., Monday through Friday, except holidays. Comments may also be faxed to this address. The fax number is (203) 468–4445.

FOR FURTHER INFORMATION CONTACT: Lieutenant Commander T.J. Walker, Chief of Port Operations, Captain of the Port, Long Island Sound, at (203) 468–4444.

SUPPLEMENTARY INFORMATION:

Regulatory History

Pursuant to 5 U.S.C. 553, good cause exists for not publishing a notice of proposed rulemaking (NPRM) and for making this rule effective in less than 30 days after publication in the **Federal Register**. The sponsor of the event did not provide the Coast Guard with the final details for the event in sufficient time to publish an NPRM or a final rule 30 days in advance. The delay encountered if normal rulemaking procedures were followed would effectively cancel the event. Cancellation of this event is contrary to the public interest since the fireworks display is for the benefit of the public.

Background and Purpose

The Lesbian & Gay Community Services Center is sponsoring a 20-minute fireworks display at Great South Bay, Sayville, New York. The fireworks display will occur on July 3, 1999, from 10:00 p.m. until 10:20 p.m. The safety zone covers all waters of Great South Bay within an 800-foot radius of the fireworks-launching site, which will be located in approximate position 40°40'.25" N, 073°04'.25" W (NAD 1983). This zone is necessary to protect the maritime community from the hazards associated with this fireworks display. Entry into or movement within this zone will be prohibited unless authorized by the Captain of the Port or his on-scene representative.

Regulatory Evaluation

This temporary final 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 FR 11040; February 26, 1979). The Coast Guard expects the economic impact of this rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This safety zone involves only a portion of West Harbor, and entry into this zone will be restricted for only 65 minutes, on July 3, 1999. Although this regulation prevents traffic from transiting West Harbor, the effect of this regulation will not be significant for several reasons: The duration of the event is limited; the event is at a late hour; all vessel traffic may safely pass around this safety zone; and extensive,