

particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections 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 179

Food additives, Food labeling, Food packaging, Radiation protection, Reporting and recordkeeping requirements, Signs and symbols.

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 179 is amended as follows:

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

1. The authority citation for 21 CFR part 179 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 343, 348, 373, 374.

2. Section 179.21(a)(1) is revised to read as follows:

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

* * * * *

(a) * * *

(1) X-ray tubes producing X-radiation from operation of the tube source at a voltage of 500 kilovolt peak or lower.

* * * * *

Dated: November 26, 1999.

L. Robert Lake,

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

[FR Doc. 99-32001 Filed 12-9-99; 8:45 am]

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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

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.

DATES: This regulation is effective December 10, 1999.

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, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, has

informed FDA of a change of sponsor address to Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the change of sponsor address.

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 congressional review requirements in 5 U.S.C 801-808.

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: 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) by revising the entry for "012799" 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, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010. * * *	* * * 012799 * * *

(2) * * *

Drug labeler code	Firm name and address
* * * 012799 * * *	* * * Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809-4010. * * *

Dated: December 2, 1999.

Claire M. Lathers,

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

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-99-082]

RIN 2115-AE46

Special Local Regulations; BellSouth Winterfest Boat Parade, Broward County, Fort Lauderdale, Florida

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Temporary Special local regulations are being adopted for the BellSouth Winterfest Boat Parade. The event will be held on December 11, 1999, on the waters of the Port Everglades turning basin and the Intracoastal Waterway from Dania Sound Light 35 (LLNR 47575) to the Pompano Beach Day Beacon 74 (LLNR 47230). The regulations are needed to provide for the safety of life on navigable waters during the event.

DATES: These regulations become effective at 5 p.m. and terminate at 10 p.m. Eastern Standard Time (EST) on December 11, 1999.

ADDRESSES: Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket [CGD07-99-082] and are available for inspection or copying at the Seventh Coast Guard District, Room 918, 909 S.E. First Avenue, Miami, FL, between 7:30 a.m. and 4 p.m. Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: BM1 Storey, Coast Guard Group Miami, Florida at (305) 535-4472.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B) and 553(d)(3), the Coast Guard finds that

good cause exists for not publishing an NPRM and making these regulations effective less than 30 days after the **Federal Register** publication. Publishing a Notice of Proposed Rulemaking and delaying the effective date would be contrary to national safety interests since immediate action is needed to minimize potential danger to the public as there will be thousands of spectator craft in the area and the event date is scheduled for December 11.

Background and Purpose

The BellSouth Winterfest Boat Parade is a nighttime parade of approximately 110 pleasure boats ranging in length from 20 feet to 200 feet decorated with holiday lights. Approximately 1000 spectator craft are anticipated. The parade will form in the staging area at the Port Everglades turning basin then proceed north on the Intracoastal Waterway (ICW) to Lake Santa Barbara where the parade will disband. The regulated area includes the staging area and the parade route. The staging area encompasses the Port Everglades turning basin, north to Dania Sound Light 35 LLNR 42865. The parade route encompasses the Intracoastal Waterway from Dania Sound Light 35 (LLNR 47575) to Pompano Beach day beacon 74 (LLNR 47230).

No anchoring is permitted in the staging area. Further, no anchoring is permitted in the vicinity of the viewing area which extends from the Sunrise Blvd Bridge south to the New River Sound Light 3 (LLNR 47240) west of the ICW. During the parade transit, these regulations prohibit nonparticipating vessels from approaching within 500 feet ahead of the lead vessel or 500 feet astern of the last participating vessel in the parade, and within 50 feet on either side of the parade, unless authorized by the Patrol Commander. After the passage of the parade participants, all vessels will be allowed to resume normal operations at the discretion of the Patrol Commander.

Regulatory Evaluation

This proposal 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. The Office of Management and Budget has not reviewed it 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 proposal to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. The regulated area will only be in effect for five hours on one day.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic effect upon a substantial number of small entities. "Small entities" include small business, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities as the regulations will only be in effect for five hours one day and the parade is a well known local event.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104-221), we offer to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. Small entities may contact the person listed under **FOR FURTHER INFORMATION CONTACT** for assistance in understanding and participating in this rulemaking. We also have a point of contact for commenting on actions by employees of the Coast Guard. Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by