

(Lat. 71° 17' 08" N, long. 156° 44' 07" W)

That airspace extending upward from 700 feet above the surface within a 6.6-mile radius of Barrow/Wiley Post-Will Rogers Memorial Airport and within 4 miles each side of the Barrow Localizer back course extending from the 6.6-mile radius to 14.6 miles east of the airport; and that airspace extending upward from 1,200 feet above the surface within a 77-mile radius of the airport extending clockwise from the Barrow VORTAC 101° radial to the 240° radial and within the area bounded by a line beginning at the Barrow VORTAC 240° radial 20 miles west to 71° 13' N 158° W to 71° 23' N 157° 48' W to 71° 25' N 156° 55' W to 71° 21' 02" N 156° 00' 41" W.

* * * * *

Issued in Anchorage, AK, on July 28, 1998.

Trent S. Cummings,

Acting Manager, Air Traffic Division, Alaskan Region.

[FR Doc. 98-20937 Filed 8-4-98; 8:45 am]

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DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

15 CFR Part 280

[Docket Number: 980623159-8159-01]

RIN 0693-AB47

Implementation of the Fastener Quality Act

AGENCY: National Institute of Standards and Technology, United States Department of Commerce.

ACTION: Final rule; correction.

SUMMARY: In the June 30, 1998, **Federal Register** notice announcing the final rule and extension of implementation date for the Fastener Quality Act, important information was inadvertently omitted from one of the amendments, which has created ambiguity in the final rule. Accordingly, the Director of the National Institute of Standards and Technology (NIST) is publishing this notice to correct that amendment.

DATES: Effective June 30, 1998.

FOR FURTHER INFORMATION CONTACT: Dr. Subhas G. Malghan, FQA Program Manager, Technology Services, National Institute of Standards and Technology, Building 820, Room 306, Gaithersburg, MD 20899, telephone number (301) 975-5120.

SUPPLEMENTARY INFORMATION: In the **Federal Register** notice published on June 30, 1998, the letter (A) was inadvertently omitted from instruction number 4. Due to this omission, it was ambiguous whether subsections (B), (C), (D), and (E) were deleted from

§ 280.810(c)(3)(i). Since the items listed in these subsections still are required, NIST is publishing this correction to the final rule to eliminate the ambiguity.

In the final rule published in the **Federal Register** on June 30, 1998 (63 FR 35507), on page 35508 in the first column, amendatory instruction number 4 is corrected to read as follows:

4. Section 280.810(c)(3)(i)(A) is revised to read as follows:

Dated: July 29, 1998.

Robert E. Hebner,

Acting Deputy Director, National Institute of Standards and Technology.

[FR Doc. 98-20809 Filed 8-4-98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 610

[Docket No. 97N-0449]

Revisions to the General Safety Test Requirements for Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule: Confirmation in part and withdrawal in part.

SUMMARY: The Food and Drug Administration (FDA) is confirming in part and withdrawing in part the provisions in the direct final rule that published in the Federal Register of April 20, 1998, to revise the general safety test (GST) requirements for biological products. FDA is confirming the part of the rule about which no significant adverse comment was received and withdrawing the part about which significant adverse comment was received.

DATES: The effective date for the revision of § 610.11(g)(1) published at 63 FR 19403 (April 20, 1998) is confirmed as September 2, 1998. The revision of § 610.11(g)(2) published at 63 FR 19403 (April 20, 1998) is withdrawn as of August 5, 1998.

FOR FURTHER INFORMATION CONTACT: Dano B. Murphy, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION: FDA published a direct final rule on April 20, 1998 (63 FR 19399), that was intended to revise the GST requirements set forth in § 610.11 (21 CFR 610.11). In response to the direct final rule, the agency received significant adverse comment about § 610.11(g)(2), the provision of the

rule that provides the administrative procedures for requesting an exemption from the GST requirements. The agency received no significant adverse comment about the addition of "cellular therapy products" to the list of products excepted from the GST in § 610.11(g)(1).

Under FDA's direct final rule procedures, the receipt of any significant adverse comment will result in the withdrawal of the direct final rule; however, FDA may adopt as final any part of a direct final rule that can be severed and is not subject to significant adverse comment. Thus, the part of this direct final rule that received significant adverse comment can be severed and is being withdrawn, effective immediately. Comments received by the agency regarding the withdrawn portion of the rule will be applied to the corresponding portion of the companion proposed rule (63 FR 19431) and will be considered in developing a final rule using the usual Administrative Procedure Act notice-and-comment procedures.

FDA is confirming § 610.11(g)(1) of the direct final rule and adding "cellular therapy products" to the list of products excepted from the GST, effective September 2, 1998.

For the reasons set forth in the preamble, the revision of § 610.11(g)(2), published at 63 FR 19403 (April 20, 1998), is withdrawn and paragraph (g)(2) is reserved.

Dated: July 29, 1998.

William K. Hubbard.

Associate Commissioner for Policy Coordination.

[FR Doc. 98-20823 Filed 8-4-98; 8:45 am]

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD07-98-033]

RIN 2115-AE46

Special Local Regulations; St. Johns River, Jacksonville, Florida

AGENCY: Coast Guard, DOT.

ACTION: Final Rule.

SUMMARY: The Coast Guard is amending the permanent special local regulations for the Annual Greater Jacksonville Kingfish Tournament, by increasing the size of the No Wake Zone on the waters of the St. Johns River and establishing the annual date of the event during the

second full week of July. The increased size of the zone is needed to safeguard the increasingly larger number of participants and other vessels transiting the St. Johns River and Sisters Creek during the Annual Greater Jacksonville Kingfish Tournament. Vessel operators should use minimum speed in this area to avoid creating wakes, unless otherwise authorized by the Captain of the Port.

DATES: This rule becomes effective on August 5, 1998.

FOR FURTHER INFORMATION CONTACT: Ensign Gary Watson, Group Mayport. Tel: (904) 247-7318.

SUPPLEMENTARY INFORMATION:

Regulatory History

On June 18, 1998, the Coast Guard published a Notice of Proposed Rulemaking concerning the changes to the permanent special local regulations for the Annual Greater Jacksonville Kingfish Tournament in the **Federal Register** (63 FR 33596). No comments were received during the comment period.

Background and Purpose

The event requiring this regulation is the Annual Greater Jacksonville Kingfish Tournament, which will be held annually during the second full week in July. Due to the large number of participants and spectator craft, a larger No Wake Zone has been proposed on the waters of the St. Johns River lying between the eastern boundary formed by St. Johns River Lighted Buoy 7 in approximate position 30-23.56N, 081-23.04W, and Lighted Buoy 8 in position 30-24.03N, 081-23.01 W, and the western boundary formed by Lighted Buoy 25 in position 30-23.40N, 081-28.26W, and Short Cut Light 26 in position 30-23.46N, 081-28.16W, with the northern and southern boundaries formed by the banks of the St. Johns River and extended north from the boundary formed by the St. Johns River and the Intracoastal Waterway, Sisters Creek, to Lighted Buoy 83 on the Intracoastal Waterway. The increased zone size is needed to safeguard vessels transiting in the St. Johns River and Sisters Creek during this event. This event will occur annually during the second full week of July, and the exact date and times will be broadcast in a Local Notice to Mariners. During each of these events, local law enforcement agents will be on scene to assist in enforcing the No Wake Zone and to monitor vessel traffic. This regulation is issued pursuant to 33 U.S.C. 1233

through 1236 as set out in the authority citation for all of Part 100.

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 not been reviewed 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 proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. Only a small amount of recreational and fishing vessel traffic is expected to be disrupted by the increased size of the No Wake Zone.

Small Entities

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

Therefore, the Coast Guard certifies under 605(b) that this rule would not have a significant economic impact on a substantial number of small entities because the No Wake Zone will only be in effect in a limited area for approximately 60 hours each year.

Collection of Information

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

Federalism

This action has been analyzed in accordance with the principles and criteria contained in Executive Order 12612, and it has been determined that the rulemaking does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Environmental Assessment

The Coast Guard has considered the environmental impact of this action consistent with Figure 2-1, paragraph (34)(h), of Commandant Instruction M16475.1C. In accordance with that section, this action has been

environmentally assessed (EA completed) and the Coast Guard has concluded that it will not significantly affect the quality of the human environment. An Environmental Assessment and Finding of No Significant Impact have been prepared and are available in the docket for inspection or copying.

List of Subjects in 33 CFR Part 100

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

Final Regulations

In consideration of the foregoing, 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 and 33 CFR 100.35.

2. Revise § 100.710 to read as follows:

§ 100.710 Annual Greater Jacksonville Kingfish Tournament; Jacksonville, Florida.

(a) *Regulated area.* A regulated area is established for the waters of the St. Johns River lying between an eastern boundary formed by St. Johns River Lighted Buoy 7 (LLNR 7145) in approximate position 30-23.56N, 081-23.04W, and Lighted Buoy 8 (LLNR 7150) in position 30-24.03N, 081-23.01W, and the western boundary formed by Lighted Buoy 25 (LLNR 7305) in position 30-23.40N, 081-28.26W, and Short Cut Light 26 (LLNR 7130 in position 30-23.46N, 081-28.16W with the northern and southern boundaries formed by the banks of the St. Johns and extended north from the boundary formed by the St. Johns River and the Intracoastal Waterway, Sisters Creek, to Lighted Buoy 83 (LLNR 38330) on the Intracoastal Waterway.

(b) *Regulations.* Vessels operating in the regulated area must operate at No Wake Speed.

(b) *Dates.* This section is effective annually during the second full week of July. Coast Guard Group Mayport will issue a Local Notice to Mariners each year announcing future specific times and dates of the event.

Norman T. Saunders,
Rear Admiral, U.S. Coast Guard Commander,
Seventh Coast Guard District.

[FR Doc. 98-20932 Filed 8-4-98; 8:45 am]

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