

distributed after September 30, 1998, even if the devices are packaged in "cold seal" packages. Device packaging that uses natural rubber only on adhesives contained in the flaps of device packaging is not considered subject to the rule. Manufacturers of devices packaged with "cold seal" adhesives may, if necessary, submit a petition for an extension of the 270-day stay.

DATES: Effective September 30, 1998, until June 27, 1999.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: John J. Farnham, Center for Devices and Radiological Health (HFZ-332), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301-594-4616.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 30, 1997 (62 FR 51021), FDA issued a final rule requiring labeling statements on medical devices, including device packaging containing natural rubber that contacts humans. The rule becomes effective on September 30, 1998. On June 5, 1998, the Health Industry Manufacturers Association (HIMA) filed a citizen petition requesting FDA to stay implementation of the final rule as it pertains to adhesives used in packaging, and packaging in general, of medical devices. On June 19, 1998, FDA denied the HIMA petition with respect to packaging in general but stated FDA would grant a stay of the effective date of paragraphs (f) and (g) of § 801.437 for 270 days from the effective date of the final rule as it pertains to device packaging that uses "cold seal" adhesives. Labeling changes required by other paragraphs of the final rule, such as elimination of the word "hypoallergenic" and inclusion of the latex content statement for devices that have natural rubber in places other than the packaging must be incorporated into the labeling of devices distributed after September 30, 1998, even if those devices are packaged in "cold seal" packages. The agency's response to HIMA's petition also clarified that FDA does not consider device packaging that uses natural rubber only on adhesives contained in the flaps of device packaging to be subject to the rule because such adhesives are not intended and are not likely to contact humans. The petition from HIMA and the agency's response are available for public examination in the Dockets Management Branch (address above)

between 9 a.m. and 4 p.m., Monday through Friday. The agency's response is also available on the FDA home page at <http://www.fda.gov/cdrh>.

This action is being taken under FDA's authority under 21 CFR 10.35(a). The Commissioner finds that this stay is in the public interest.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 801 is amended as follows:

PART 801—LABELING

1. The authority citation for 21 CFR part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 357, 360i, 360j, 371, 374.

2. Section 801.437 is amended by adding the following note to the end of the section:

§ 801.437 User labeling for devices that contain natural rubber.

* * * * *
Note to § 801.437: Paragraphs (f) and (g) are stayed until June 27, 1999, as those regulations relate to device packaging that uses "cold seal" adhesives.

Dated: August 20, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07-98-023]

RIN 2115-AE84

Regulated Navigation Area; San Juan Harbor, San Juan, PR

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary regulated navigation area in San Juan Harbor in the vicinity of La Puntilla in San Juan, PR. This regulated navigation area is needed to protect personnel, vessels, and equipment during the construction of piers at Coast Guard Base San Juan from the hazards created by the wakes of passing vessel traffic. By establishing this temporary regulation, the Coast Guard expects to reduce the risk of personnel injury and property damage.

DATES: This rule is effective from August 10, 1998, through August 10, 1999.

FOR FURTHER INFORMATION CONTACT:

LT D.R. XIRAU, Assistant Chief Port Operations Department, USCG Marine Safety Office San Juan at (787) 729-6800, ext 320.

SUPPLEMENTARY INFORMATION:

Background and Purpose

These regulations create a temporary regulated navigation area requiring all vessels to operate at no-wake speed in the vicinity of Coast Guard Base San Juan. These regulations are necessary to provide for the safety of personnel, vessels, and equipment during the construction of several piers at Coast Guard Base San Juan. Coast Guard Base San Juan is located at La Puntilla in Old San Juan, at a junction of major channels in the San Juan Harbor. The Coast Guard believes that a significant risk exists under current conditions because wakes cause damage to vessels and the piers, and create major safety hazards to personnel working on the piers and on board moored vessels.

Heavy wakes can cause damage to property while undergoing construction at Coast Guard Base San Juan. Vessel hulls, cleats, stanchions, and gangways have been bent or parted in the past. In addition, electrical shore ties and fueling hoses have been pulled loose, creating very hazardous situations. By establishing a temporary no-wake speed zone in the vicinity of La Puntilla, the risks to personnel and property inherent to wakes will be minimized during the construction.

In accordance with 5 U.S.C. 533, a notice of proposed rulemaking was not published for this regulation and good cause exists for making it effective in less than 30 days from the date of publication. Following normal rulemaking procedures would have been impractical. Construction is scheduled to begin in a few days and there was not sufficient time to publish proposed rules prior to the construction event nor to provide for a delayed effective date.

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 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 10e of the regulatory policies and procedures of DOT is unnecessary as the regulations only require minimum steerage way speeds and do not limit the amount of incoming and outgoing vessels.

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 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).

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 as there are no limits imposed on the quantity of incoming or outgoing vessels.

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 implication to warrant the preparation of a Federalism Assessment.

Environmental Analysis

The Coast Guard has considered the environmental impact of this action and has determined pursuant to figure 2-1, paragraph (34)(g) of Commandant Instruction M16475.1C, that this rule is categorically excluded from further environmental documentation. A Categorical Exclusion Determination and Environmental Analysis Checklist have been prepared and are available in the docket for inspection and copying.

List of Subjects in 33 CFR Part 165

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

Temporary Regulations

In consideration of the foregoing, the Coast Guard amends amend Subpart F

of Part 165 of Title 33, Code of Federal Regulations, 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.

2. Add a new § 165.T07-023 to read as follows:

§ 165.T07-023 Regulated Navigation Area; San Juan Harbor, San Juan, Puerto Rico.

(a) *Regulated Area.* The following is a Regulated Navigation Area: All the waters of San Juan Harbor bounded by the following geographic coordinates: Lighted Buoy #11 (LLNR 30805) in approximate position (18-27.31N, 066-07.01W; east to Puerto Rico Ports Authority Pier #3 in approximate position 18-27.40N, 066-06.43W; south to Lighted Buoy "A" (LLNR 30845) in approximate position 18-26.55N, 066-06.26W; west to Can Buoy "A" (LLNR 30815) in approximate position 18-27.01N, 066-06.59W; and thence north to the point of origin. All coordinates referenced use Datum: NAD 83.

(b) *Regulations.* (1) Unless otherwise authorized by the Captain of the Port, San Juan, Puerto Rico, all vessels operating in the regulated area must travel at no-wake speed. The general regulations in § 165.13 of this part apply.

(2) Violations of this regulated navigation area should be reported to the Captain of the Port, San Juan, PR.

(c) *Dates.* This section is effective from August 10, 1998 through August 10, 1999.

Dated: August 10, 1998.

R.C. Olsen, Jr.,

Captain U.S. Coast Guard, Commander, Seventh Coast Guard District, Acting.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01-98-115]

RIN AA97

Safety and Security Zones; Presidential Visit, Martha's Vineyard, MA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary moving safety

and security zones, with identical boundaries, around the President of the United States during his vacation on Martha's Vineyard, Massachusetts. The security zone is needed to safeguard the President, the public, and property from sabotage or other subversive acts, accidents, or other causes of a similar nature. The safety zone is necessary to protect the spectators and the President's entourage. Entry into the zones is prohibited unless authorized by the Captain of the Port, Providence Rhode Island or the Coast Guard Presidential Security Detail Senior Duty Officer.

DATES: This regulation is effective from August 17, 1998, through August 31, 1998.

ADDRESSES: Documents relating to this temporary final rule are available for inspection and copying at U.S. Coast Guard Marine Safety Office Providence, 20 Risho Avenue, East Providence, RI 02914. Normal office hours are between 8:00 a.m. and 4:00 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: LT Ronald Cantin, U.S. Coast Guard, Marine Safety Field Office, Cape Cod, MA, at (508) 968-6556.

SUPPLEMENTARY INFORMATION:

Drafting Information. The principal person involved in drafting this document is LT.R.J. Cantin, Project Manager.

Regulatory History

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking was not published (NPRM) for this regulation and good cause exists for making it effective in less than 30 days after **Federal Register** publication. Due to the sensitive and unpredictable nature of the President's schedule, the Coast Guard received insufficient notice to publish proposed rules in advance of the event. Publishing a NPRM and delaying its effective date would be contrary to the public interest since immediate action is needed to protect the President and the public.

Background and Purpose

From August 17, 1998, through August 31, 1998, President Clinton will be vacationing on Martha's Vineyard, MA. While vacationing, the President may be involved in myriad activities including boating or fishing trips, swimming, jogs along the beach, dinners at waterfront restaurants, golfing, all of which will place him on or in close proximity to the navigable waters of the United States. This temporary rule establishes moving safety and security