

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. This proposed rule will relieve a burden and simplify the marketing of these devices by exempting the devices from premarket notification requirements. The guidance document is based on existing review practices and will not impose new burdens on manufacturers of these devices. The agency, therefore, certifies that the proposed rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

VII. Submission of Comments

You may submit written or electronic comments regarding this proposal to the Division of Dockets Management (see **ADDRESSES**). Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. You should identify comments with the docket number found in brackets in the heading of this document. Any comments FDA receives will be available in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

VIII. Paperwork Reduction Act of 1995

FDA concludes that this proposed rule contains no collection of information that is subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995.

IX. Proposed Effective Date

FDA is proposing that any final rule based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

X. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Gastroenterology and Urology Devices Panel of the Medical Devices Advisory Committee transcript, August 7, 1997.
2. Lewis, J. H. et al., "A Way to Help Your Patients Who Use Vacuum Devices," *Contemporary Urology*, vol. 3, No. 12: 15–24, 1991.
3. Montague, D. K. et al., "Clinical Guidelines Panel on Erectile Dysfunction; Summary Report on the Treatment of Erectile Dysfunction," *Journal of Urology*, 156, 2007–2011, 1996.
4. "NIH Consensus Statement-Impotence," National Institutes of Health, vol. 10, No. 4, 1992.

List of Subjects in 21 CFR Part 876

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, FDA proposes that 21 CFR part 876 be amended to read as follows:

PART 876—GASTROENTEROLOGY—UROLOGY DEVICES

1. The authority citation for 21 CFR part 876 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

2. Section 876.1 is amended by adding paragraph (e) to read as follows:

§ 876.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at <http://www.fda.gov/cdrh/guidance.html>.

3. Section 876.5020 is added to subpart F to read as follows:

§ 876.5020 External penile rigidity devices.

(a) *Identification.* External penile rigidity devices are devices intended to create or maintain sufficient penile rigidity for sexual intercourse. External penile rigidity devices include vacuum pumps, constriction rings, and penile splints which are mechanical, powered, or pneumatic devices.

(b) *Classification.* Class II (special controls). The devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The special control for these devices is the FDA guidance document entitled "Class II Special Controls Guidance Document: External Penile Rigidity Devices; Draft Guidance for Industry and FDA." See § 876.1(e) for the availability of this guidance document.

Dated: March 4, 2004.

Beverly Cherniak Rothstein,

Acting Deputy Director for Policy and Regulations, Center for Devices and Radiological Health.

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD07–04–037]

RIN 1625–AA09

Drawbridge Operation Regulations; Hobe Sound Bridge (SR 708), Atlantic Intracoastal Waterway, mile 996.0, Hobe Sound, Martin County, FL

AGENCY: Coast Guard, DHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to change the operating regulations of the Hobe Sound Bridge (SR 708) across the Atlantic Intracoastal Waterway, mile 996.0 in Hobe Sound, Florida. This proposed rule would require the drawbridge to open on a 20-minute schedule from 7 a.m. to 6 p.m., daily. This proposed action would improve the movement of vehicular traffic while not unreasonably interfering with the movement of vessel traffic.

DATES: Comments and related material must reach the Coast Guard on or before May 17, 2004.

ADDRESSES: You may mail comments and related material to Commander (obr), Seventh Coast Guard District, 909 S.E. 1st Avenue, Room 432, Miami, FL, 33131, who maintains the public docket for this rulemaking. Comments and material received from the public, as well as documents indicated in this preamble as being available in the docket, will become part of this docket and are available for inspection or copying at Commander (obr), Seventh Coast Guard District, between 7:30 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Mr. Michael Lieberum, Project Officer, Seventh Coast Guard District, Bridge Branch, at (305) 415–6744.

SUPPLEMENTARY INFORMATION:

Request for Comments

We encourage you to participate in this rulemaking by submitting comments and related material. If you do so, please include your name and address, identify the docket number for this rulemaking [CGD07–04–037], indicate the specific section of this document to which each comment applies, and give the reason for each comment. Please submit all comments and related material in an unbound format, no larger than 8½ by 11 inches, suitable for copying. If you would like to know they reached us, please enclose

a stamped, self-addressed postcard or envelope. We will consider all comments and material received during the comment period. We may change this proposed rule in view of them.

Public Meeting

We do not now plan to hold a public meeting. But you may submit a request for a meeting by writing to the Bridge Branch at the address under **ADDRESSES** explaining why one would be beneficial. If we determine that one would aid this rulemaking, we will hold one at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The existing regulations of the Hobe Sound Bridge (SR 708), mile 996.0, at Hobe Sound, published in 33 CFR 117.5 require the draw to open on signal.

On June 18, 2002, the Town of Jupiter Island requested that the Coast Guard review the existing regulations governing the operation of the Hobe Sound Bridge, because the Town contended that those regulations were not meeting the needs of vehicle and vessel traffic.

On August 28, 2002, the Coast Guard issued a test deviation published in the **Federal Register** (67 FR 55115). This test deviation was effective from November 1, 2002, until January 27, 2003. The test deviation allowed a change to the current bridge regulations by allowing the bridge to open on the hour, 20 minutes after the hour, and 40 minutes after the hour from 7 a.m. to 6 p.m. daily. We received 67 comments in reference to this deviation. Sixty comments were for the 20 minute schedule; three comments requested that the schedule be changed to an hour and half-hour; two comments were against the proposed schedule; and one of those requested that, if it were to be made permanent, it be limited to the winter season. One comment requested a permanent exemption from the regulations for all commercial vessels and one comment suggested enforcement of current regulations.

The Coast Guard proposes to make the 20-minute schedule published in the test deviation permanent, based on prior bridge logs, which indicated that the bridge opened two to three times an hour, and comments received from the public during the test deviation period. This proposed schedule may benefit both vessel and vehicle traffic by allowing for the opportunity to plan trips in conjunction with the 20-minute scheduled bridge openings. The hour and half schedule suggested by three comments appears to place additional unnecessary restrictions on navigation.

The need for a seasonal summer and winter schedule does not appear to have any additional benefits for either vehicle or vessel traffic in this area as the prior traffic counts did not significantly differ between the summer and winter seasons. However, we may request additional traffic counts based on comments related to this NPRM. One comment requested an exemption for commercial vessels. However, with the exception of tugs and tugs with tows and Public Vessels of the United States, the Coast Guard does not normally exempt classes of vessels from regulations governing bridge operations.

Discussion of Proposed Rule

This proposed rule would require the Hobe Sound Bridge (SR 708), mile 996.0, at Hobe Sound to open on signal; except that, from 7 a.m. to 6 p.m., the draw need open only on the hour, 20 minutes after the hour, and 40 minutes after the hour.

Regulatory Evaluation

This proposed rule is not a "significant regulatory action" under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 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 Homeland Security (DHS).

We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. This proposed rule would modify the existing bridge schedule to allow for efficient vehicle traffic flow and provide scheduled openings for vessel traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this proposed rule would have a significant economic impact on a substantial number of small entities. The term "small entities" comprises 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 proposed rule would not have a significant economic impact on a substantial number of small entities. This proposed rule would affect the following entities, some of which

may be small entities: the owners or operators of vessels needing to transit the Intracoastal Waterway in the vicinity of Hobe Sound Bridge, persons intending to drive over the bridge and nearby business owners. The proposed rule offers frequent, scheduled openings for vessel traffic, 3 times per hour from 7 a.m. to 6 p.m., and will meet the reasonable needs of navigation throughout the affected times. Vehicle traffic and small business owners in the area will benefit from the increased traffic flow that regularly scheduled openings will offer this area.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this proposed rule would economically affect it.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this proposed rule so that they can better evaluate its effects on them and participate in the rulemaking. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

Collection of Information

This proposed rule would call for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this proposed rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of

\$100,000,000 or more in any one year. Though this proposed rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This proposed rule would not affect a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This proposed rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this proposed rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

Indian Tribal Governments

This proposed rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this proposed rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. It has not been designated by the Administrator of the Office of Information and Regulatory Affairs as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Environment

We have analyzed this proposed rule under Commandant Instruction

M16475.1D, which guides the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321–4370f), and have concluded that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this proposed rule is categorically excluded, under figure 2–1, paragraph (32)(e) of the Instruction, from further environmental documentation. Under figure 2–1, paragraph (32)(e) of the Instruction, an "Environmental Analysis Check List" and a "Categorical Exclusion Determination" are not required for this proposed rule.

List of Subjects in 33 CFR Part 117

Bridges.

Regulations

For the reasons discussed in the preamble, the Coast Guard proposes to amend 33 CFR part 117 as follows:

PART 117—DRAWBRIDGE OPERATION REGULATIONS

1. The authority citation for Part 117 continues to read as follows:

Authority: 33 U.S.C. 499; Department of Homeland Security Delegation No. 0170.1; 33 CFR 1.05–1(g); section 117.255 also issued under the authority of Pub. L. 102–587, 106 Stat. 5039.

2. Add § 117.261(q) to read as follows:

§ 117.261 Atlantic Intracoastal Waterway from St. Marys River to Key Largo.

* * * * *

(q) *Hobe Sound Bridge (SR 708), mile 996.0, at Hobe Sound.* The draw shall open on signal; except that, from 7 a.m. to 6 p.m., the draw need open only on the hour, 20 minutes after the hour, and 40 minutes after the hour.

* * * * *

Dated: February 13, 2004.

Harvey E. Johnson, Jr.,

Rear Admiral, U.S. Coast Guard, Commander, Seventh Coast Guard District.

[FR Doc. 04–6049 Filed 3–16–04; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 60 and 63

[FRL–7637–7]

Supplemental Notice and Extension of the Comment Period for the Proposed National Emission Standards for Hazardous Air Pollutants; and, in the Alternative, Proposed Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Announcement of public hearing and extension of public comment period.

SUMMARY: The EPA is announcing that a public hearing will be held for the Supplemental Notice of Proposed Rule (Supplemental Proposal) for the January 30, 2004, Proposed National Emission Standards for Hazardous Air Pollutants (69 FR 4652); and, in the Alternative, Proposed Standards of Performance for New and Existing Stationary Sources: Electric Utility Steam Generating Units (Proposed Utility Mercury Reductions Rule).

The Supplemental Proposal includes a model cap and trade program and monitoring and reporting requirements for the January 30, 2004, proposal. The Supplemental Proposal was signed by the EPA Administrator on February 25, 2004, and is posted on the EPA Web site (provided under **ADDRESSES**).

The public hearing will be held in Denver, Colorado. The hearing is scheduled for March 31, 2004. Persons wishing to present oral testimony for the Supplemental Proposal may do so at this hearing. Details of the hearing are reiterated below.

DATES: *Public Hearing.* The public hearing will be held on March 31, 2004.

Comments. The public comment period for the Proposed Utility Mercury Reductions Rule, which was published on January 30, 2004, is extended to April 30, 2004, in order to provide the public additional time to submit comments and supporting information.

ADDRESSES: *Public Hearing.* The hearing will be held at the following location: Hyatt Regency Denver, 1750 Welton Street, Denver, Colorado, 80202, (303) 295–1234.

Comments. Written comments on the Supplemental Proposal may also be submitted to EPA electronically, by mail, by facsimile, or through hand delivery/courier. Please refer to the proposal for the addresses and detailed instructions.