

net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because the proposed rule does not impose any new requirements, it will impose no significant economic impact on any small entities. The agency certifies that this proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement or analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

VIII. Paperwork Reduction Act of 1995

FDA tentatively concludes that this proposed rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

IX. Submission of Comments

Interested persons may, on or before April 5, 1999, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted except individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

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, it is proposed that 21 CFR part 876 be amended 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 876.5020 is added to subpart F to read as follows:

§ 876.5020 External penile rigidity devices.

(a) *Identification.* An external penile rigidity device is a device intended to help manage erectile dysfunction. External penile rigidity devices consist of vacuum pumps, constriction rings, and penile splints. The vacuum pump has a cylinder that is placed over the penis and produces an erection by creating a vacuum around the penis. The constriction ring is placed around the base of the erect penis, keeping the blood in the penis and thus, maintaining the erection. Penile splints are rigid or flexible support structures that are externally attached to the penis to physically support the penis during sexual intercourse.

(b) *Classification.* Class II (special controls).

Dated: December 17, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-34733 Filed 12-31-98; 8:45 am]

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DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2560

RIN 1210-AA61

Public Hearing on Proposed Claims Procedures

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Notice of public hearing.

SUMMARY: The purpose of this Notice is to inform interested persons that the Department of Labor will hold a public hearing on both February 17 and 18, 1999, and, if necessary, on February 19, 1999, regarding the adoption of regulations governing the processing of employee benefit plan claims under section 503 of the Employee Retirement Income Security Act of 1974, as amended, (ERISA). The Department published in the **Federal Register** proposed changes to the requirements governing the processing and appeal of claims by employee benefit plans under ERISA (63 FR 48390, September 9, 1998). The purpose of the public hearing is to obtain and consider further information and views on the proposed regulation and the effects of the proposed claim procedure changes on plans, plan participants, plan sponsors and service providers.

DATES: The public hearing is scheduled for February 17 and 18, 1999, and, if necessary, February 19, 1999. The hearing will begin at 10 a.m. on each of these days. Requests to testify at the hearing should be received by the Department no later than January 15, 1999. Oral statements will be limited to 10 minutes. Individuals with disabilities, who need special accommodations, should contact Jeffrey J. Turner by February 5, 1999, at the address below.

ADDRESSES: Requests to testify at the hearing should be submitted to: Jeffrey J. Turner, Office of Regulations and Interpretations, Room N-5669, Pension and Welfare Benefits Administration, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210. All requests will be open to public inspection at the Public Documents Room, Pension and Welfare Benefits Administration, Room N-5638, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210 from 8:30 a.m. to 5:30 p.m. The hearing will be held in the U.S. Department of Labor Auditorium, 200 Constitution Avenue, NW, Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Jeffrey J. Turner, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, U.S. Department of Labor, at (202) 219-8671. This is not a toll-free number.

SUPPLEMENTARY INFORMATION: On September 9, 1998, the Department of Labor (the Department) published a notice of proposed rulemaking in the **Federal Register** (63 FR 48390) revising the minimum requirements for benefit claims procedures of employee benefit plans covered under Title I of the Employee Retirement Income Security Act (ERISA). In that notice, the Department invited interested persons to submit written comments concerning the proposed regulations on or before November 9, 1998. On October 30, 1998, in response to requests from the public for additional time to prepare comments, the Department extended the comment period through December 9, 1998 (63 FR 58335). A number of comments submitted in response to the solicitation for public comment requested that the Department hold a public hearing on proposed regulation. Because of the complexity and importance of the issues involved, the Department believes that it is appropriate to hold a public hearing on the proposed regulation. The information obtained from the hearing will assist the Department in assessing whether, and to what extent, the

proposed regulation should be modified in conjunction with the adoption of a final rule.

Notice of Public Hearing

Notice is hereby given that a public hearing regarding the Department of Labor's proposed claims procedure regulations (63 FR 48390, September 9, 1998) is scheduled for February 17 and 18, 1999, and, if necessary, February 19, 1999. The hearing will begin at 10:00 a.m. on each of these days. Oral presentations will be limited to 10 minutes, but an extended statement may be submitted for the record. Requests to testify should be submitted to the address identified above, no later than January 15, 1999. It is requested that persons testifying on behalf of plans, plan sponsors, and service providers be prepared to answer questions pertaining to specific claims processing procedures and practices (e.g., methods of notification, time frames, etc.) of their plans, their clients' plan(s) or their members' plans.

Signed at Washington, DC, this 23rd day of December, 1998.

Leslie B. Kramerich,

*Deputy Assistant Secretary For Policy,
Pension and Welfare Benefits Administration,
U.S. Department of Labor.*

[FR Doc. 98-34819 Filed 12-31-98; 8:45 am]

BILLING CODE 4510-29-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD01-98-162]

RIN 2115-AE46

Special Local Regulations: Empire State Regatta, Albany, NY

AGENCY: Coast Guard, DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Coast Guard proposes to revise the Special Local Regulations for the Empire State Regatta. This action is necessary to update the course location and effective period for this annual event. This action is intended to restrict vessel traffic in a portion of the Hudson River.

DATES: Comments must be received on or before March 5, 1999.

ADDRESSES: Comments may be mailed to the Waterways Oversight Branch (CGD01-98-162), Coast Guard Activities New York, 212 Coast Guard Drive, Staten Island, New York 10305, or deliver them to room 205 at the same address between 8 a.m. and 3 p.m.,

Monday through Friday, except Federal holidays.

The Waterways Oversight Branch of Coast Guard Activities New York maintains the public docket for this rulemaking. Comments, and documents as indicated in this preamble, will become part of this docket and will be available for inspection or copying at room 205, Coast Guard Activities New York, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT:

Lieutenant J. Lopez, Waterways Oversight Branch, Coast Guard Activities New York (718) 354-4193.

SUPPLEMENTARY INFORMATION:

Request for Comments

The Coast Guard encourages interested persons to participate in this rulemaking by submitting written data, views, or arguments. Persons submitting comments should include their names and addresses, identify this rulemaking (CGD01-98-162) and the specific section of this document to which each comment applies, and give the reason for each comment. Please submit two copies of all comments and attachments in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. Persons wanting acknowledgment of receipt of comments should enclose stamped, self-addressed postcards or envelopes.

The Coast Guard will consider all comments received during the comment period. It may change this proposed rule in view of the comments.

The Coast Guard plans no public hearing. Persons may request a public hearing by writing to the Waterways Oversight Branch at the address under **ADDRESSES**. The request should include the reasons why a hearing would be beneficial. If it determines that the opportunity for oral presentations will aid this rulemaking, the Coast Guard will hold a public hearing at a time and place announced by a later notice in the **Federal Register**.

Background and Purpose

The Albany Rowing Center sponsors this annual crewing race with approximately 300 rowers competing in this event. The sponsor expects no spectator craft for this event. The race will take place on the Hudson River in the vicinity of Albany, New York. The sponsor held the race in a new location in 1998 and is planning on holding the event in this new location in the future. This proposed new course provides better viewing for spectators on shore, and it is also easier for the sponsor to

set up. The proposed regulated area encompasses all waters of the Hudson River from the Albany Rensselaer Swing Bridge, river mile 146.2, to Light 224 (LLNR 39015), river mile 147.5, located approximately 75 yards north of the I-90/Patruon Island Bridge. The new race course is 800 yards smaller than the current course.

The proposed effective period (§ 100.104(b)) states the event will be held on the first weekend of June. The current effective period states the event will be held on the first or second weekend of June. This proposed rule reduces uncertainty the current regulation causes regarding the date of the event. The special local regulations (§ 100.104(c)) remains unchanged.

Discussion of Proposed Rule

The proposed Special Local Regulation is for the Empire State Regatta held on the Hudson River in the vicinity of Albany, New York. The Special Local Regulations for this event are located at 33 CFR § 100.104. The sponsor held this event further north in 1998 from the area published in § 100.104 and is planning on holding the event in this new location in the future. This event will be held on the first weekend of June. The current regulation states the event will be held on the first or second weekend of June. This rule is proposed to change the course location and the event date published in § 100.104, provide for the safety of life on navigable waters during the event, and to give the marine community the opportunity to comment on the regulated area.

Regulatory Evaluation

This proposed 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. Although this regulation prevents traffic from transiting a portion of the Hudson River during the race, the effect of this regulation will not be significant for several reasons: this is an annual marine event currently published in 33 CFR § 100.104, the limited amount of commercial traffic in this area of the