

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]  
BILLING CODE 4160-01-F

#### 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