DC 20580. If possible, comments should also be submitted in electronic form, pursuant to the instructions contained in the NPRM. Comments should be identified as ''Pay-Per-Call Rule Review—Comment. FTC File No. R6111016.'' Notifications of interest in participating in the public workshop should be addressed to Carole Danielson, Division of Marketing Practices, Federal Trade Commission, 600 Pennsylvania Ave., NW, Washington, DC 20580. Materials cited in the NPRM are available for public inspection at the FTC's Public Reference Section, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Adam G. Cohen, (202) 326–3411, Marianne K. Schwanke, (202) 326–3165, or Carole I. Danielson, (202) 326–3115, Division of Marketing Practices, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC.

SUPPLEMENTARY INFORMATION: On October 30, 1998, at 63 FR 58524, the Commission published a request for comment on its Notice of Proposed Rulemaking (''NPRM'') regarding proposed amendments to its Pay-Per-Call Rule. The Pay-Per-Call Rule governs the advertising and operation of pay-per-call services, and establishes billing dispute procedures for those services as well as for other telephone-billed purchases. The comment period is currently scheduled to close on January 8, 1999, and the public workshop is scheduled for February 25 and 26, 1999.

On December 14, 1998, a diverse group representing a broad cross-section of interests [1] filed a Joint Request for Extension of Comment Deadline, in which they requested an extension of the comment period by thirty (30) days to February 8, 1999. The parties indicated that additional time was required to prepare thorough, thoughtful responses to the comprehensive and complex set of proposals contained in the NPRM. Subsequently, the Commission received two additional requests for extension; the first also seeking an additional 30 days,[2] and the second seeking a 60-day extension of the comment period.[3]

The Commission is mindful of the need to resolve this matter expeditiously. However, the Commission is also aware that the issues raised by the NPRM are complex and it welcomes as much substantive input as possible to facilitate its decision-making process. Accordingly, in order to provide sufficient time for these and other interested parties to prepare useful comments, the Commission has decided to extend the deadline for comments by sixty (60) days, until March 10, 1999. The Commission has likewise rescheduled the public workshop for May 20 and 21, 1999.

It should be noted that the NPRM as published in the Federal Register on October 30, 1998, omitted italicization that the Commission had included in many places throughout the text for emphasis or organizational clarity. The italics were erroneously removed in the printing process. An accurate and properly italicized version of the Commission's NPRM is available in the Commission's Public Reference room and on the Commission's Web page, at www.ftc.gov. Commenters wishing to cite to the NPRM, however, should cite to the **Federal Register** version of the document.

Finally, for the convenience of interested parties, certain materials cited in the NPRM will be made available for public inspection at the FTC's Public Reference Section, Room 130, Federal Trade Commission, 600 Pennsylvania Ave., NW, Washington, DC 20580. These materials include, but are not limited to, pleadings and other filings from Commission and state enforcement actions, as well as newspaper and magazine articles. In addition, the Commission may make available other materials that may be useful to commenters, such as consumer complaints. The Commission may continue to update these materials periodically, as appropriate.

List of Subjects in 16 CFR Part 308

Advertising, 900 telephone numbers, Pay-per-call services, Telephone, Telephone-billed purchases, Toll-free numbers, Trade practices.

Authority: Pub. L. 102–556, 106 Stat. 4181 (15 U.S.C. 5701, *et seq.*); Sec. 701, Pub. L. 104–104, 110 Stat. 56 (1996).

By the direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 98–34408 Filed 12–31–98; 8:45 am]

BILLING CODE 6750–01–M

[1] The Joint Request signatories include: the American Association of Retired Persons, the Billing Reform Task Force, the Coalition to Ensure Responsible Billing, AT&T Corp., the Promotion Marketing Association, and the Teleservices Industry Association.

[2] On December 15, 1998, a request for a 30-day extension was received from the law firm of Kelley Drye & Warren, LLP, on behalf of Cable & Wireless (West Indies) Ltd.

[3] The Electronic Commerce Association submitted a request on behalf of its members, on December 16, 1998, requesting a 60-day extension of the comment period.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. 98N–1111]

External Penile Rigidity Devices; Proposed Classification for the External Penile Rigidity Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to classify the generic type of external penile rigidity device including constriction rings, vacuum pumps, and penile splints for the management of erectile dysfunction. These devices fit on, over, or around the penis to support, promote, or maintain sufficient penile rigidity for sexual intercourse. Under the proposal, the external penile rigidity devices would be classified into class II (special controls). The agency is issuing in this document the recommendations of the Gastroenterology-Urology Advisory Panel regarding the classification of these devices. After considering public comments on the proposed classification, FDA will publish a final regulation classifying this device. This action is being taken to establish sufficient regulatory controls that will provide reasonable assurance of the safety and effectiveness of this device.

DATES: Written comments by April 5, 1999. See section V of this document for the proposed effective date of a final rule based on this document.

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

FOR FURTHER INFORMATION CONTACT: Donald St. Pierre, Center for Devices and Radiological Health (HFZ–470), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2194.

SUPPLEMENTARY INFORMATION:

I. Background

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 301 *et. seq.*), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) (Pub. L. 94–295) and the Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629), established a comprehensive system for the regulation of medical devices intended for human

use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under the 1976 amendments, class II devices were defined as those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish performance standards to provide such assurance. The SMDA broadened the definition of class II devices to mean those devices for which there is insufficient information to show that general controls themselves will assure safety and effectiveness, but for which there is sufficient information to establish special controls to provide such assurance. Special controls may include performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and any other appropriate actions the agency deems necessary (section 513 (a)(1)(B) of the act).

Under section 513 of the act, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as preamendment devices, are classified after FDA has met three requirements: (1) FDA has received a recommendation from a device classification panel (an FDA advisory committee); (2) FDA has published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) FDA has published a final regulation classifying the device. FDA has classified most preamendment devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendment devices, are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless and until FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendment device that has been classified into class III may be marketed, by means of premarket notification procedures, without submission of a premarket approval application until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Consistent with the act and the regulations, FDA consulted with the Gastroenterology-Urology Advisory Panel (the Panel), an FDA advisory committee, regarding the classification of these external penile rigidity devices. During a public meeting held Thursday, August 7, 1997, the Panel discussed the usage and history of external penile rigidity devices, specifically constriction rings, vacuum pumps, and penile splints used for the management of erectile dysfunction.

The panel discussed the usage and composition of each of these devices. Constriction rings are devices that are placed around the base of the erect penis for the duration of sexual intercourse to restrict the flow of venous blood leaving the penis. Constriction rings are usually elastic bands or adjustable loops, and they must be designed to include handles or tabs so that they can be readily removed from the penis.

Vacuum erection systems are devices consisting of vacuum pumps (either hand-operated or motorized) and penile cylinders. They produce an erection by creating a vacuum around the flaccid penis to induce passive blood flow into the penis, thus producing an erection. Once a satisfactory erection is obtained, the user often places a constriction ring around the base of the erect penis, prior to removing the vacuum cylinder, in order to maintain the erection.

Penile splints are rigid or flexible support structures that are externally attached to or placed along the penis to physically support the penis during sexual intercourse.

External penile rigidity devices are preamendment devices not included as part of the gastroenterology and urology devices that were classified in 1983. FDA has reviewed marketing applications for these devices through the premarket notification or 510(k) process.

The premarket notifications or 510(k) reviews involved verifying that the labeling of these devices adequately informs both patients and practitioners on their safe use. Additionally, the premarket notifications or 510(k) reviews ensure that the device has certain key safety features, such as handles on constriction rings for quick removal and safe limits on the maximum vacuum pressure that can be generated.

Pain and/or discomfort, bruising, hemorrhage and/or hematoma formation, penile injury, and penile gangrene (if blood flow is restricted too long) are risks and possible side effects associated with the use of these external penile rigidity devices.

Currently, these devices are offered both over the counter and by prescription. While the over the counter and prescription devices are similar, the differences distinguishing the over the counter and prescription devices are in their labeling and packaging.

II. Recommendation of the Panel

During the public meeting held on Thursday, August 7, 1997, the Panel made the following recommendation for the classification of external penile rigidity devices into class II.

A. Identification

Penile rigidity devices are generic external devices that include constriction rings, vacuum pumps, and penile splints for the management of erectile dysfunction. These devices fit on, over, or around the penis to support, promote, or maintain sufficient penile rigidity for sexual intercourse.

B. Recommended Classification of the Panel

The Panel recommended that external penile rigidity devices be classified into class II, special controls devices. Based on the available information, the Panel believes that, in addition to general controls, the following special controls regarding labeling recommendations are necessary to provide reasonable assurance of the safety and effectiveness of the external penile rigidity devices with regard to the identified risks to health of this device:

1. Labeling for the external penile rigidity device should include the device name, corporation name, address, telephone number, intended use, disposable/single use status (if applicable), a description of the device (including dimensional specifications), and directions for use;

2. The labeling should include the indications for use and identification of the population(s) for whom the device is appropriate;

3. The directions for use should contain comprehensive instructions on how to size, place, operate, remove, and clean the device;

4. The labeling should include the warning: ''If you cannot achieve an erection that is sufficient for sexual intercourse, see your doctor before using

this device to be sure that it will not aggravate another medical condition you might have. Also, your doctor will be able to check you for some of the most common causes of erection problems, such as diabetes, multiple sclerosis, cirrhosis of the liver, chronic kidney failure, or alcoholism.''; and

5. Relevant contraindications, warnings, and precautions should be included in the labeling of the device along with possible methods of resolution of the problems/risks associated with the use of the device. Specifically, we believe that the warning and cautionary statements listed in section II.B.1.2.and 3 of this document by device type should be addressed in the labeling for these devices using terminology well-understood by the average layperson as follows:

1. Information Relevant to Constriction Rings

Use of the device should be restricted to 30 minutes. Do not fall asleep wearing the constriction ring. Prolonged use of the constriction bands (i.e., without removal) may cause permanent injury to the penis.

Consult your physician should any complications occur and discontinue use of the device if such conditions persist.

The user should allow 60 minutes between uses.

Use the largest size constriction ring which maintains an erection.

Constriction rings should not be used under the influence of alcohol or drugs.

Constriction rings are not intended for use as a contraceptive/birth control.

Frequent use of constriction rings may result in bruising at the base of the penis (where the shaft of the penis meets the pubic area).

Do not use the device if you have a decreased ability to sense pain in the area of the penis because pain may occur as a warning sign that the device may be causing injury.

Do not use the device if you have insufficient manual dexterity to easily remove the device.

2. Information Relevant to Vacuum Pumps

Consult your physician should any complications occur and discontinue use of the device if such conditions persist.

The user should apply the minimum amount of vacuum pressure necessary to achieve an erection.

The user should stop using the vacuum pump if pain occurs.

Vacuum pumps should not be used under the influence of alcohol or drugs.

Use of a vacuum pump may bruise or rupture the blood vessels either immediately below the surface of the skin or within the deep structures of the penis or scrotum, resulting in hemorrhage and/or the formation of a hematoma.

Misuse of a vacuum pump may aggravate already existing medical conditions such as Peyronie's disease, priapism, and urethral strictures.

Misuse of the vacuum pump could result in swelling of the penis and/or serious permanent injury to the penis.

Do not use an electrically powered vacuum pump in or near water.

Vacuum pumps should not be used by men who take anticoagulants (blood thinners).

Vacuum pumps do not provide a satisfactory erection in every man. If erection satisfactory for intercourse is not achieved the user should consult with a physician familiar with such devices to determine the cause.

Do not use the device if you have a decreased ability to sense pain in the area of the penis, because pain may occur as a warning sign that the device may be causing injury.

3. Information Relevant to Penile Splints

Consult a physician if any injuries occur to either yourself or your sexual partner, and discontinue use of the device if such conditions persist.

C. Summary of Reasons for Recommendation

The Panel believes the external penile rigidity devices should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

D. Summary of Data Upon Which the Recommendation is Based

The panel based its recommendation on their knowledge and experience in addition to published literature on external penile rigidity devices (Refs. 2 through 4).

E. Risks to Health

Pain and/or discomfort, bruising, hemorrhage and/or hematoma formation, penile injury and penile gangrene (if blood flow is restricted too long) are risks and possible side effects associated with the use of these external penile rigidity devices. FDA believes, however, that the special controls regarding labeling recommendations will provide reasonable assurance of the safety and effectiveness of the external penile rigidity devices.

III. Proposed Classification

FDA agrees with the Panel recommendation for classification of these devices under class II. FDA believes the external penile rigidity devices should be classified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

IV. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday though 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.

V. Proposed Effective Date

The agency proposes that any final rule that may issue based on this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

VI. Environmental Impact

The agency has determined under 21 CFR 25.24(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), as amended by subtitle D of the Small Business Regulatory Fairness Act of 1996 (Pub. L. 104–121), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize

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