Notices of intent to appear and accompanying evidence, if any, must be sent to James L. DeMarce, Director, Division of Coal Mine Workers' Compensation, Room C–3520, Frances Perkins Building, 200 Constitution Avenue, N.W., Washington, D.C. 20210; FAX Number 202–219–8568.

FOR FURTHER INFORMATION CONTACT: James L. DeMarce, Director, Division of Coal Mine Workers' Compensation, (202) 219–6692.

SUPPLEMENTARY INFORMATION:

Filing of Notices of Intent To Appear and Evidence Before the Hearing

The notice of intent to appear must contain the following information:

1. The name, address, organization, and telephone number of each person to appear;
2. The capacity in which the person will appear;
3. The approximate amount of time required for the presentation;
4. A brief statement of the position that will be taken with respect to the proposed regulations;
5. Whether the party intends to testify based on medical, scientific, economic or technical evidence. If so, three copies of that evidence must be attached to the notice of intent to appear.

ESA will review each notice of intent to appear in light of the amount of time requested. In those instances when the requested amount of time exceeds 20 minutes, ESA will determine, in its sole discretion, whether the amount of time requested is supported by the accompanying documentation. If not, the participant will be notified of that fact prior to the hearing.

Conduct and Nature of the Hearing

The hearing will commence at 9:00 a.m. on July 22, 1997. At that time, the presiding officer, an Administrative Law Judge, will resolve any procedural matters relating to the hearing which are delegated to his discretion in this notice. It is ESA's intent to provide interested members of the public with an opportunity to make effective oral presentations and to insure that these presentations proceed expeditiously, without procedural restraints which might impede or protract the rulemaking process. The hearing is primarily for the purpose of information gathering and therefore will be an informal administrative proceeding rather than an adjudicative one. The formal rules of evidence will not apply. The hearing is also intended to facilitate the development of a clear, accurate and complete record. Thus, questions of relevance, procedure and participation generally will be decided so as to favor development of the record.

The order of appearance of persons who have filed notices of intent to appear will be determined by ESA. Only the Department may ask questions of witnesses. The presiding officer will make no decision or recommendation on the merits of ESA's proposal, but rather will be responsible for ensuring that the hearing proceeds at a reasonable pace and in an orderly manner. The presiding officer, therefore, will have all the powers necessary and appropriate to conduct a full and fair informal hearing, including the powers:

1. To regulate the course of the proceedings;
2. To dispose of procedural requests, objections and comparable matters;
3. To confine the presentations to pertinent and relevant matters; and
4. To regulate the conduct of those present at the hearing by appropriate means.

Individuals with disabilities, who need special accommodations, should contact James L. DeMarce by Tuesday, July 8 at the address indicated in this notice.

Contents of the Rulemaking Record

This rulemaking record will remain open through August 21, 1997 (62 FR 27000). A verbatim transcript of the hearing will be prepared and made a part of the record. It will be available for public inspection at the Office of the Solicitor, Division of Black Lung Benefits, 200 Constitution Avenue, NW., Suite N–2605, Washington, DC 20210. Members of the public may also arrange with the court reporter to purchase their own copies. All notices of intent to appear at the hearing and accompanying evidence, if any, will also be made a part of the record and will be available for public inspection at the above address. ESA will also accept additional written comments and other appropriate data from any interested party, including those not presenting oral testimony, until expiration of the comment period.

Signed at Washington, DC, this 12th day of June, 1997.

Gene Karp,

Deputy Assistant Secretary for Employment Standards.

[FR Doc. 97–15942 Filed 6–17–97; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 884, and 890

[Docket No. 94N–0418]

Retaining Certain Preamendment Class III Devices in Class III

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to retain the following preamendment class III devices in class III: Lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair. Manufacturers of these referenced preamendment class III devices were requested, by an order published in the **Federal Register,** to submit a summary of, and a citation to, all information known or otherwise available to them respecting their devices, including adverse safety or effectiveness information concerning the devices that had not been submitted under the Federal Food, Drug, and Cosmetic Act (the act). FDA believes that these devices should remain in class III because insufficient information exists to determine that special controls would provide reasonable assurance of their safety and effectiveness, and/or these devices present a potential unreasonable risk of illness or injury.

DATES: Submit written comments by September 16, 1997. FDA proposes that any final rule that may issue based on this proposal become effective 30 days after the date of publication of the final rule.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 321 *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 classes of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are class I (general controls), class II (special controls), and class III (premarket approval). Generally, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), and devices marketed on or after that date that are substantially equivalent to such devices, have been classified by FDA. This proposed rule refers to both the devices that were in commercial distribution before May 28, 1976, and the substantially equivalent devices that were in commercial distribution on or after that date, as ''preamendment devices.''

The SMDA added new section 515(i) (21 U.S.C. 360e(i)) to the act. This section requires FDA to order manufacturers of preamendment class III devices, for which no final regulation has been issued requiring the submission of premarket approval applications (PMA's), to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i) (hereinafter referred to as ''515(i) orders).'' Section 519 of the act requires manufacturers, importers, and distributors to maintain records and to report information that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury, or that a malfunction of the device is likely to cause death or serious injury on recurrence. Section 515(i)(2) of the act directs FDA to publish proposed and final regulations when devices, subject to 515(i) orders, are to remain in class III or be reclassified into class I or class II. Section 515(i)(3) of the act directs FDA to establish a schedule for the issuance of rules requiring the submission of PMA's for devices remaining in class III.

Accordingly, in the **Federal Register** of August 14, 1995 (60 FR 41984), FDA issued an order under section 515(i) of the act requiring manufacturers of 27 preamendment class III devices to submit to FDA a summary of, and citation to, all information known or otherwise available to them respecting such devices, including adverse safety or effectiveness information concerning the devices that had not been submitted under section 519 of the act. FDA requested this information in order to determine, for each device, whether the classification of the device should be revised, or whether a regulation requiring the submission of PMA's for the device should be issued.

Based on the lack of safety and effectiveness information submitted in response to the section 515(i) order, FDA proposes that the devices discussed in sections I.A., B., and C of this document remain in class III because, for each of these devices: (1) Insufficient information exists to determine that general controls alone, or that general controls together with special controls, would provide reasonable assurance of the device's safety and effectiveness, and/or (2) these devices present a potential unreasonable risk of illness or injury.

A. Lung Water Monitor (21 CFR 868.2450)

In the **Federal Register** of November 2, 1979 (44 FR 63292 at 63341), FDA proposed to classify the lung water monitor into class III, in accordance with the recommendation of the Anesthesiology Device Classification Panel (the Panel). The lung water monitor is intended to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance by means of electrodes placed on the patient's chest. The Panel recommended classifying this device into class III because the Panel believed that the lung water monitor presented a potential unreasonable risk of illness or injury. The Panel also believed that insufficient information existed to determine whether performance standards would be adequate to provide reasonable assurance of the safety and effectiveness of the device. In accordance with the Panel's recommendation, FDA issued a final rule in the **Federal Register** of July 16, 1982 (47 FR 31130 at 31142) classifying the lung water monitor into class III.

The safety risks associated with the lung water monitor using a double indicator dilution technique include: (1) Typical risks associated with the placement of a catheter, such as thrombosis and hematomas; (2) electrical shock; (3) misdiagnosis if the device is not calibrated or does not accurately measure changes in lung fluid volume; and (4) inappropriate therapy. The safety risks associated with the lung water monitor using thoracic impedance include: (1) Electrical shock; (2) misdiagnosis; and (3) inappropriate therapy.

The Panel's original concerns regarding the clinical effectiveness of the technology have not been resolved. The literature that has been published has not produced clear results regarding the effectiveness of this device; it does suggest, however, that this device may have some potential use in certain specific diseases. Unfortunately, this information is based on the results of a lung water computer device that is no longer marketed. Alternative technology, such as pulmonary artery catheterization, chest x-ray, and echocardiography are now in common use for evaluation of congestive heart failure or pulmonary edema. Because insufficient information, i.e. lack of information regarding the technology, particularly the effectiveness of the technology, exists to determine either that general controls alone, or that general controls together with special controls would provide reasonable assurance of the device's safety and effectiveness, FDA proposes that the device remain in class III.

Furthermore, FDA concludes that this device continues to present the same potential unreasonable risk of illness or injury that was first identified by the original classification panel because the agency has not received any additional information regarding the safety and effectiveness of this device. FDA, therefore, proposes that this device remain in class III.

B. Powered Vaginal Muscle Stimulator for Therapeutic Use (21 CFR 884.5940)

In the **Federal Register** of April 3, 1979 (44 FR 19894 at 19969), FDA proposed to classify into class III, in accordance with the recommendation of the Obstetrical and Gynecological Device Classification Panel (the Ob/Gyn Panel), the powered vaginal muscle stimulator for therapeutic use intended to increase muscle tone and strength in the treatment of sexual dysfunction. The Ob/Gyn Panel recommended classifying this device into class III because the Ob/Gyn Panel believed that the satisfactory performance of the device had not been demonstrated. The Ob/Gyn Panel also questioned the usefulness of this device when used in the treatment of sexual dysfunction. In fact, only one citation in the clinical literature was referenced in FDA's proposed rule classifying the device and that one reference indicated that vaginal muscle stimulation in the treatment of sexual dysfunction had fallen into disuse. In accordance with the Ob/Gyn Panel's recommendation, FDA issued a final rule in the **Federal Register** of February 26, 1980 (45 FR 12684) classifying the powered vaginal muscle stimulator for therapeutic use into class III.

The safety risks associated with the powered vaginal muscle stimulator for

therapeutic use intended to increase muscle tone and strength in the treatment of sexual dysfunction include: (1) Electrical shock; (2) burns; (3) irritation, trauma, hemorrhage, and perforation; and (4) adverse tissue reaction.

FDA is unaware of any manufacturers who currently market powered vaginal muscle stimulators for treatment of sexual dysfunction. Only one manufacturer of this device was ever registered. That one manufacturer, however, is no longer registered. Moreover, no manufacturers responded to the 515(i) order requesting the submission of information and announcing FDA's intention to keep this device in class III.

In the absence of information from manufacturers, FDA conducted a thorough search of the medical literature, including clinical texts, on the treatment of sexual dysfunction using powered vaginal muscle stimulation. No references were identified by this search. In addition, review of the available information on this device shows that there is no evidence in the literature demonstrating the effectiveness of this device for the treatment of sexual dysfunction. As a result, FDA proposes that the powered vaginal muscle stimulator intended for the treatment of sexual dysfunction remain in class III because insufficient information exists to determine either that general controls alone or that general controls together with special controls would provide reasonable assurance of the device's safety and effectiveness.

Moreover, because FDA has not received any additional information regarding the safety and effectiveness of this device in response to the 515(i) order, FDA concludes that this device continues to present the same potential unreasonable risks of illness or injury that were first identified by the original classification panel. FDA, therefore, proposes that this device remain in class III.

C. Stair-Climbing Wheelchair (21 CFR 890.3890)

In the **Federal Register** of August 28, 1979 (44 FR 50497), FDA proposed to classify into class III, in accordance with the recommendation of the Physical Medicine Device Classification Panel (the Physical Medicine Panel), the stair-climbing wheelchair intended for medical purposes to provide mobility to persons restricted to a sitting position. The device is intended to climb stairs by means of two endless belt tracks that are lowered from under the chair and adjusted to the angle of the stairs. The Physical Medicine Panel recommended classifying this device into class III because it believed that satisfactory performance of the device had not been demonstrated, and, therefore, it is not possible to establish an adequate performance standard for the device. The Physical Medicine Panel also noted that the device was experimental, and data to support its safe and effective use were not available. Subsequently, in the **Federal Register** of November 23, 1983 (48 FR 53032 at 53047), FDA issued a final rule classifying into class III the stair-climbing wheelchair, in accordance with the recommendation of the Physical Medicine Panel.

The safety risks associated with the stair-climbing wheelchair include bodily injury. If the device fails the disabled patient could fall and be seriously or fatally injured.

To date, the agency has not received any information in response to the 515(i) order. Because the agency has not received any additional information regarding the safety and effectiveness of this device, FDA concludes that the satisfactory performance of the device still remains to be demonstrated. It is still not possible to establish adequate special controls for the device. Therefore, FDA proposes that the stair-climbing wheelchair remain in class III.

Furthermore, FDA concludes that this device continues to present the same potential unreasonable risks of illness or injury that were first identified by the original classification panel because the agency has not received any additional information regarding the safety and effectiveness of this device. Insufficient information exists to determine either that general controls alone or that general controls together with special controls would provide reasonable assurance of the safety and effectiveness of this device. FDA, therefore, proposes that this device remain in class III.

II. Environmental Impact

The agency has determined under 21 CFR 25.24(a)(8) 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.

III. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). 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 this proposal simply retains class III devices in class III, the agency 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.

IV. Congressional Review

This rule is not a major rule under the congressional review provisions of Subtitle E of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121).

V. Comments

Interested persons may, on or before September 16, 1997 submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, written comments regarding this proposal. Two copies of any comments are to be submitted, except that 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.

This proposed rule is issued under sections 513, 515(i), and 701(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c, 360e(i), and 701(a)) and under authority of the Commissioner of Food and Drugs.

Dated: June 4, 1997.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 97–15993 Filed 6–17–97; 8:45 am]

BILLING CODE 4160–01–F