regulatory burden on the System, the FCA will ensure that safety and soundness is maintained and that its regulations and policies implement the Act.

Dated: August 11, 1998.

Floyd Fithian,

Secretary, Farm Credit Administration Board.

[FR Doc. 98–22100 Filed 8–17–98; 8:45 am]

BILLING CODE 6705–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 868, 884, and 890

[Docket No. 98N–0564]

Medical Devices; Effective Date of Requirement for Premarket Approval for Three Class III Preamendments Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; opportunity to request a change in classification.

SUMMARY: The Food and Drug Administration (FDA) is proposing to require the filing of a premarket approval application (PMA) or a notice of completion of a product development protocol (PDP) for the following three class III preamendments devices: Lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair. The agency also is summarizing its proposed findings regarding the degree of risk of illness or injury designed to be eliminated or reduced by requiring the devices to meet the statute's approval requirements and the benefits to the public from the use of the devices. In addition, FDA is announcing the opportunity for interested persons to request that the agency change the classification of any of the devices based on new information. This action implements certain statutory requirements.

DATES: Written comments by November 16, 1998; request for a change in classification by September 2, 1998. FDA intends that, if a final rule based on this proposed rule is issued, PMA's will be required to be submitted within 90 days of the effective date of the final rule.

ADDRESSES: Submit written comments or requests for a change in classification to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Janet L. Scudiero, Center for Devices and Radiological Health (HFZ–410), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1184.

SUPPLEMENTARY INFORMATION:

I. Background—Regulatory Authorities

The Federal Food, Drug, and Cosmetic Act (the act), 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 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 preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendments 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 the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with 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.

Section 515(b)(1) of the act (21 U.S.C. 360e(b)(1)) established the requirement that a preamendments device that FDA has classified into class III is subject to premarket approval. A preamendments class III device may be commercially distributed without an approved PMA or a notice of completion of a PDP until 90 days after FDA issues a final rule requiring premarket approval for the device, or 30 months after final classification of the device under section 513 of the act, whichever is later. Also, a preamendments device subject to the rulemaking procedure under section 515(b) of the act is not required to have an approved investigational device exemption (IDE) (see 21 CFR part 812) contemporaneous with its interstate distribution until the date identified by FDA in the final rule requiring the submission of a PMA for the device. At that time, an IDE is required only if a PMA has not been submitted or a PDP completed.

Section 515(b)(2)(A) of the act provides a proceeding to issue a final rule to require premarket approval shall be initiated by publication of a notice of proposed rulemaking containing: (1) The regulation; (2) proposed findings with respect to the degree of risk of illness or injury designed to be eliminated or reduced by requiring the device to have an approved PMA or a declared completed PDP and the benefit to the public from the use of the device; (3) an opportunity for the submission of comments on the proposed rule and the proposed findings; and (4) an opportunity to request a change in the classification of the device based on new information relevant to the classification of the device.

Section 515(b)(2)(B) of the act provides that if FDA receives a request for a change in the classification of the device within 15 days of the publication of the notice, FDA shall, within 60 days of the publication of the notice, consult with the appropriate FDA advisory committee and publish a notice denying the request for change in reclassification or announcing its intent to initiate a proceeding to reclassify the device under section 513(e) of the act. Section 515(b)(3) of the act provides that FDA shall, after the close of the comment period on the proposed rule and consideration of any comments received, issue a final rule to require premarket approval, or publish a notice terminating the proceeding together with the reasons for such termination. If FDA terminates the proceeding, FDA is required to initiate reclassification of the device under section 513(e) of the act, unless the reason for termination is that the device is a banned device under section 516 of the act (21 U.S.C. 360f).

If a proposed rule to require premarket approval for a preamendments device is finalized, section 501(f)(2)(B) of the act (21 U.S.C.

351(f)(2)(B)) requires that a PMA or notice of completion of a PDP for any such device be filed within 90 days of the date of issuance of the final rule or 30 months after the final classification of the device under section 513 of the act, whichever is later. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, commercial distribution of the device is required to cease. The device may, however, be distributed for investigational use if the manufacturer, importer, or other sponsor of the device complies with the IDE regulations. If a PMA or notice of completion of a PDP is not filed by the later of the two dates, and no IDE is in effect, the device is deemed to be adulterated within the meaning of section 501(f)(1)(A) of the act, and subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334) if its distribution continues. Shipment of devices in interstate commerce will be subject to injunction under section 302 of the act (21 U.S.C. 332), and the individuals responsible for such shipment will be subject to prosecution under section 303 of the act (21 U.S.C. 333). In the past, FDA has requested that manufacturers take action to prevent the further use of devices for which no PMA has been filed and may determine that such a request is appropriate for the class III devices that are the subjects of this regulation.

The act does not permit an extension of the 90-day period after issuance of a final rule within which an application or a notice is required to be filed. The House Report on the 1976 amendments states that:

> [t]he thirty month 'grace period' afforded after classification of a device into class III * * * is sufficient time for manufacturers and importers to develop the data and conduct the investigations necessary to support an application for premarket approval (H. Rept. 94–853, 94th Cong., 2d sess. 42 (1976)).

The SMDA added section 515(i) to the act requiring FDA to review the classification of preamendments class III devices for which no final rule has been issued requiring the submission of PMA's and to determine whether or not each device should be reclassified into class I or class II or remain in class III. For devices remaining in class III, SMDA directed FDA to develop a schedule for issuing regulations to require premarket approval. The SMDA does not, however, prevent FDA from proceeding immediately to rulemaking under section 515(b) of the act on specific devices, in the interest of public health, independent of the procedures of section 515(i). Indeed, proceeding directly to rulemaking under section 515(b) of the act is consistent with Congress' objective in enacting section 515(i), i.e., that preamendments class III devices for which PMA's have not been required either be reclassified to class I or class II or be subject to the requirements of premarket approval. Moreover, in this proposal, interested persons are being offered the opportunity to request reclassification of any of the devices.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA issued a notice of availability of a preamendments class III devices strategy document. The strategy set forth FDA's plans for implementing the provisions of section 515(i) of the act for preamendments class III devices for which FDA had not yet required premarket approval. FDA divided this universe of devices into three groups.

Group 1 devices are devices that FDA believes raise significant questions of safety and/or effectiveness but are no longer used or are in very limited use. FDA's strategy is to call for PMA's for all Group 1 devices in an omnibus section 515(b) of the act rulemaking action. In the **Federal Register** of September 7, 1995 (60 FR 46718), FDA implemented this strategy by proposing requiring the filing of a PMA or a notice of completion of a PDP for 43 class III preamendments devices. Subsequently, in the **Federal Register** of September 27, 1996 (61 FR 50704), FDA called for the filing of a PMA or a notice of completion of a PDP for 41 preamendments class III devices. (Due to public comment, the agency is reconsidering its position on the two remaining devices subject to the September 7, 1995 proposal).

Group 2 devices are devices that FDA believes have a high potential for being reclassified into class II. In the **Federal Register** of August 14, 1995 (60 FR 41986), and of June 13, 1997 (62 FR 32355), FDA issued an order under section 515(i) of the act requiring manufacturers to submit safety and effectiveness information on these Group 2 devices so that FDA can make a determination as to whether the devices should be reclassified.

Group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA intends to issue proposed rules to require the submission of PMA's for the 15 high priority devices in this group in accordance with the schedule set forth in the strategy document. In the **Federal Register** of August 14, 1995 (60 FR 41984), and of June 13, 1997 (62 FR 32352), FDA issued an order under section 515(i) of the act for the 27 remaining Group 3 devices requiring manufacturers to submit safety and effectiveness information so that FDA can make a determination as to whether the devices should be reclassified or retained in class III.

In the **Federal Register** of June 18, 1997 (62 FR 33044), FDA published a proposed rule to retain the following three devices in class III: Lung water monitor; powered vaginal muscle stimulator for therapeutic use; and stair-climbing wheelchair. Interested persons were given until September 16, 1997, to comment on the proposed rule. During the comment period, the agency received no comments on the proposed rule. FDA has, therefore, concluded that insufficient information exists to establish special controls to provide reasonable assurance of the safety and effectiveness of these devices and/or that these devices present a potential unreasonable risk of illness or injury. Accordingly, in the **Federal Register** of June 30, 1998 (63 FR 35516), FDA published a final rule to retain these devices in class III.

II. Dates New Requirements Apply

In accordance with section 515(b) of the act, FDA is proposing to require that a PMA or a notice of completion of a PDP be filed with the agency for class III devices within 90 days after issuance of any final rule based on this proposal. An applicant whose device was legally in commercial distribution before May 28, 1976, or whose device has been found to be substantially equivalent to such a device, will be permitted to continue marketing such class III devices during FDA's review of the PMA or notice of completion of the PDP. FDA intends to review any PMA for the device within 180 days, and any notice of completion of a PDP for the device within 90 days of the date of filing. FDA cautions that, under section 515(d)(1)(B)(i) of the act, the agency may not enter into an agreement to extend the review period for a PMA beyond 180 days unless the agency finds that ''* * * the continued availability of the device is necessary for the public health.''

FDA intends that, under § 812.2(d), the preamble to any final rule based on this proposal will state that, as of the date on which the filing of a PMA or a notice of completion of a PDP is required to be filed, the exemptions in § 812.2(c)(1) and (c)(2) from the requirements of the IDE regulations for preamendments class III devices will cease to apply to any device that is: (1) Not legally on the market on or before that date, or (2) legally on the market on or before that date but for which a PMA

or notice of completion of a PDP is not filed by that date, or for which PMA approval has been denied or withdrawn.

If a PMA or notice of completion of a PDP for a class III device is not filed with FDA within 90 days, after the date of issuance of any final rule requiring premarket approval for the device, commercial distribution of the device must cease. The device may be distributed for investigational use only if the requirements of the IDE regulations regarding significant risk devices are met. The requirements for significant risk devices include submitting an IDE application to FDA for its review and approval. An approved IDE is required to be in effect before an investigation of the device may be initiated or continued. FDA, therefore, cautions that IDE applications should be submitted to FDA at least 30 days before the end of the 90-day period after the final rule to avoid interrupting investigations.

III. Proposed Findings With Respect to Risks and Benefits

As required by section 515(b) of the act, FDA is publishing its proposed findings regarding: (1) The degree of risk of illness or injury designed to be eliminated or reduced by requiring that these devices have an approved PMA or a declared completed PDP; and (2) the benefits to the public from the use of the devices.

These findings are based on the reports and recommendations of the advisory committees (panels) for the classification of these devices along with any additional information that FDA has discovered. Additional information can be found in the following proposed and final rules published in the **Federal Register** on the dates given below, classifying these devices: Anesthesiology Devices, 21 CFR part 868 (44 FR 63292, November 2, 1979, and 47 FR 31130, July 16, 1982); Obstetrical and Gynecology Devices, 21 CFR part 884 (44 FR 19894, April 3, 1979, and 45 FR 12682, February 26, 1980); and Physical Medicine Devices, 21 CFR part 890 (44 FR 50458, August 28, 1979, and 48 FR 53032, November 23, 1983).

IV. Devices Subject to This Proposal

A. Lung Water Monitor (21 CFR 868.2450)

1. Identification

A lung water monitor is a device used to monitor the trend of fluid volume changes in a patient's lung by measuring changes in thoracic electrical impedance (resistance to alternating current) by means of electrodes placed on a patient's chest.

2. Summary of Data

The Anesthesiology Device Classification Panel recommended that the lung water monitor intended to monitor the trend of fluid volume changes in a patient's lung be classified into class III based on the panel members personal knowledge of, and experience with, the device and the lack of available clinical data. The panel noted that there is no acceptable quantitative procedure for measuring changes in lung fluid volume. FDA agreed and continues to agree with the panel's recommendation that the device be classified into class III.

3. Risks to Health

a. *Incorrect diagnosis*: If the device is not calibrated or does not accurately measure changes in lung fluid volume, misdiagnosis of the patient's condition may result in inappropriate therapy.

b. *Electrical shock*: If the device malfunctions or is not properly grounded, the patient may receive an electrical shock.

c. *Allergic reaction:* The adhesive backing on the electrodes applied to the chest may cause skin irritation or an allergic reaction.

d. *Typical risks of catheter placement*: Thrombosis and hematoma formation may occur.

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

1. Identification

A powered vaginal muscle stimulator for therapeutic use is an electrically powered device designed to stimulate directly the muscles of the vagina with pulsating electrical current. This device is intended and labeled for therapeutic use in increasing muscular tone and strength in the treatment of sexual dysfunction. This generic type of device does not include devices used to treat urinary incontinence.

2. Summary of Data

The Obstetrical and Gynecological Device Classification Panel recommended that the powered vaginal muscle stimulator for therapeutic use intended for treatment of sexual dysfunction be classified into class III based on their familiarity with the device and the lack of information on the effectiveness of the device. FDA agreed and continues to agree with the panel's recommendation. The agency noted that the device had fallen into disuse and that the published data are not adequate to demonstrate the safety and effectiveness of the device.

3. Risks to Health

a. *Burns*: Improper voltage control of the device could result in electrical burns when the device comes in contact with vaginal tissue.

b. *Electrical shock*: Malfunction of the device could result in electrical shock to the patient.

c. *Irritation, tissue trauma, hemorrhage, and perforation*: Improper shape, or other design shortcomings, of the device could cause injury to vaginal tissue.

d. *Adverse tissue reaction*: Material or substances in the device could cause a local tissue or systematic reaction when the device contacts the patient.

C. Stair-Climbing Wheelchair (21 CFR 890.3890)

1. Identification

A stair-climbing wheelchair is a device with wheels that is 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.

2. Summary of Data

The Physical Medicine Device Classification Panel recommended that the device intended for medical purposes to provide mobility to persons restricted to a sitting position be classified into class III based on the potential hazards associated with the device, the panel members familiarity with the device, the lack of sufficient data to support the safety and effectiveness of the device, and the literature. FDA agreed and continues to agree with the panel's recommendation that the device be classified into class III.

3. Risks to Health

The primary risk to health is that of bodily injury. If the device fails, the disabled patient could fall and be seriously injured.

V. PMA Requirements

A PMA for these devices must include the information required by section 515(c)(1) of the act. Such a PMA should also include a detailed discussion of the risks identified previously, as well as a discussion of the effectiveness of the device for which premarket approval is sought. In addition, a PMA must include all data and information on: (1) Any risks known, or that should be reasonably known, to the applicant that have not been identified in this document; (2) the effectiveness of the device that is the subject of the

application; and (3) full reports of all preclinical and clinical information from investigations on the safety and effectiveness of the device for which premarket approval is sought.

A PMA should include valid scientific evidence ''obtained from well-controlled clinical studies, with detailed data,'' in order to provide reasonable assurance of the safety and effectiveness of the device for its intended use (see 21 CFR 860.7(c)(2)).

Applicants should submit any PMA in accordance with FDA's ''Premarket Approval (PMA) Manual.'' This manual is available upon request from FDA, Center for Devices and Radiological Health, Division of Small Manufacturers Assistance (HFZ–220), 1350 Piccard Dr., Rockville, MD 20850. This manual is also available on the world wide web at http://www.fda.gov/cdrh.

VI. PDP Requirements

A PDP for any of these devices may be submitted in lieu of a PMA, and must follow the procedures outlined in section 515(f) of the act. A PDP should provide: (1) A description of the device; (2) preclinical trial information (if any); (3) clinical trial information (if any); (4) a description of the manufacturing and processing of the devices; (5) the labeling of the device; and (6) all other relevant information about the device. In addition, the PDP must include progress reports and records of the trials conducted under the protocol on the safety and effectiveness of the device for which the completed PDP is sought. Applicants should submit any PDP in accordance with FDA's ''PDP Comprehensive Outline with Attachments.'' This outline is available upon request from FDA, Center for Devices and Radiological Health, Office of Device Evaluation (HFZ–400), 9200 Corporate Blvd., Rockville, MD 20850. The outline and other PDP information is also available on the world wide web at http://www.fda.gov/cdrh/pdp.

VII. Request for Comments with Data

Interested persons may, on or before November 16, 1998, submit to the Dockets Management Branch (address above) 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.

VIII. Opportunity to Request a Change in Classification

Before requiring the filing of a PMA or notice of completion of a PDP for a device, FDA is required by section 515(b)(2)(A)(i) through (b)(2)(A)(iv) of the act and 21 CFR 860.132 to provide an opportunity for interested persons to request a change in the classification of the device based on new information relevant to the classification. Any proceeding to reclassify the device will be under the authority of section 513(e) of the act.

A request for a change in the classification of these devices is to be in the form of a reclassification petition containing the information required by § 860.123 (21 CFR 860.123), including new information relevant to the classification of the device, and shall, under section 515(b)(2)(B) of the act, be submitted by September 2, 1998.

The agency advises that, to ensure timely filing of any such petition, any request should be submitted to the Dockets Management Branch (address above) and not to the address provided in § 860.123(b)(1). If a timely request for a change in the classification of these devices is submitted, the agency will, by October 19, 1998, after consultation with the appropriate FDA advisory committee and by an order published in the **Federal Register**, either deny the request or give notice of its intent to initiate a change in the classification of the device in accordance with section 513(e) of the act and 21 CFR 860.130 of the regulations.

IX. Environmental Impact

The agency has determined under 21 CFR 25.30(h) 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.

X. 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), 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.

If a rule has a significant economic impact on a substantial number of small entities, the Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because FDA believes that there is little or no interest in marketing these devices, the agency certifies that the proposed rule, if issued as a final rule, will not have a significant impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Paperwork Reduction Act of 1995

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

List of Subjects

21 CFR Parts 868, 884, and 890

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 parts 868, 884, and 890 be amended as follows:

PART 868—ANESTHESIOLOGY DEVICES

1. The authority citation for 21 CFR part 868 continues to read as follows:

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

2. Section 868.2450 is amended by revising paragraph (c) to read as follows:

§ 868.2450 Lung water monitor.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule in the **Federal Register**), for any lung water monitor that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule in the **Federal Register**), been found to be substantially equivalent to

a lung water monitor that was in commercial distribution before May 28, 1976. Any other lung water monitor shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

3. The authority citation for 21 CFR part 884 continues to read as follows:

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

4. Section 884.5940 is amended by revising paragraph (c) to read as follows:

§ 884.5940 Powered vaginal muscle stimulator for therapeutic use.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule in the **Federal Register**), for any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule in the **Federal Register**), been found to be substantially equivalent to any powered vaginal muscle stimulator for therapeutic use that was in commercial distribution before May 28, 1976. Any other powered vaginal muscle stimulator for therapeutic use shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

PART 890—PHYSICAL MEDICINE DEVICES

5. The authority citation for 21 CFR part 890 continues to read as follows:

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

6. Section 890.3890 is amended by revising paragraph (c) to read as follows:

§ 890.3890 Stair-climbing wheelchair.

* * * * *

(c) *Date PMA or notice of completion of PDP is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before (date 90 days after date of publication of the final rule in the **Federal Register**), for any stair-climbing wheelchair that was in commercial distribution before May 28, 1976, or that has, on or before (date 90 days after date of publication of the final rule in the **Federal Register**), been found to be substantially equivalent to any stair-climbing wheelchair that was in commercial distribution before May 28, 1976. Any other stair-climbing wheelchair shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: August 5, 1998.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98–21999 Filed 8–17–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–209446–82]

RIN 1545–AT52

Pass Through of Items of an S Corporation to its Shareholders

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed regulations relating to the pass through of items of an S corporation to its shareholders, the adjustments to the basis of stock of the shareholders, and the treatment of distributions by an S corporation. Changes to the applicable law were made by the Subchapter S Revision Act of 1982, the Tax Reform Act of 1984, the Tax Reform Act of 1986, the Technical and Miscellaneous Revenue Act of 1988, and the Small Business Job Protection Act of 1996. These proposed regulations provide the public with guidance needed to comply with the applicable law and will affect S corporations and their shareholders. This document also contains a notice of public hearing on these proposed regulations.

DATES: Written comments must be received by November 16, 1998. Outlines of topics to be discussed at the public hearing scheduled for Tuesday, December 15, 1998, at 10 a.m. must be received by Tuesday, November 24, 1998.

ADDRESSES: Send submissions to: CC:DOM:CORP:R (REG–209446–82), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered between the hours of 8 a.m. and 5 p.m. to: CC:DOM:CORP:R (REG–209446–82), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC. Alternatively, taxpayers may submit comments electronically via the Internet by selecting the ''Tax Regs'' option on the IRS Home Page, or by submitting comments directly to the IRS Internet site at http://www.irs.ustreas.gov/prod/tax_regs/comments.html. The public hearing will be held in room 2615, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the regulations under section 1366, Deane M. Burke or Terri A. Belanger, (202) 622–3070; concerning the regulations under sections 1367 and 1368, Brenda Stewart, (202) 622–3120; concerning submissions and the hearing, Michael Slaughter, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, OP:FS:FP, Washington, DC 20224. Comments on the collection of information should be received by October 19, 1998. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the Internal Revenue Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up cost and costs of operation, maintenance, and purchase of service to provide information.