

regulatory authority beginning July 1, 1998, to have OHA attorney advisors conduct certain prehearing proceedings and issue fully favorable decisions where appropriate under the rules. In order to provide for an uninterrupted continuance of that authority for the additional period we believe appropriate, and to ensure that we retain the ability to manage the hearings process appropriately, we find that it is in the public interest to make these rules effective upon publication.

#### Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that these rules do not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, the rules are not subject to OMB review.

#### Regulatory Flexibility Act

We certify that these regulations will not have a significant economic impact on a substantial number of small entities because they affect only individuals. Therefore, a regulatory flexibility analysis as provided in the Regulatory Flexibility Act, as amended, is not required.

#### Paperwork Reduction Act

These regulations impose no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.006, Supplemental Security Income)

#### List of Subjects

##### 20 CFR Part 404

Administrative practice and procedure, Death benefits, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

##### 20 CFR Part 416

Administrative practice and procedure, Aged, Blind, Disability benefits, Public assistance programs, Supplemental Security Income (SSI), Reporting and recordkeeping requirements.

Dated: June 23, 1998.

**Kenneth S. Apfel,**

*Commissioner of Social Security.*

For the reasons set out in the preamble, subpart J of part 404 and subpart N of part 416 of chapter III of title 20 of the Code of Federal Regulations are amended as set forth below.

#### PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950—)

Subpart J is amended as follows:

1. The authority citation for subpart J of part 404 continues to read as follows:

**Authority:** Secs. 201(j), 205(a), (b), (d)-(h), and (j), 221, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 401(j), 405(a), (b), (d)-(h), and (j), 421, 425, and 902(a)(5)); 31 U.S.C. 3720A; sec. 5, Pub. L. 97-455, 96 Stat. 2500 (42 U.S.C. 405 note); secs. 5, 6(c)-(e), and 15, Pub. L. 98-460, 98 Stat. 1802 (42 U.S.C. 421 note).

2. Section 404.942 is amended by revising paragraph (g), to read as follows:

##### § 404.942 Prehearing proceedings and decisions by attorney advisors.

\* \* \* \* \*

(g) *Sunset provision.* The provisions of this section will no longer be effective on April 1, 1999, unless they are extended by the Commissioner of Social Security by publication of a final rule in the **Federal Register**.

#### PART 416—SUPPLEMENTAL SECURITY INCOME FOR THE AGED, BLIND, AND DISABLED

Subpart N is amended as follows:

1. The authority citation for subpart N continues to read as follows:

**Authority:** Sec. 702(a)(5), 1631, and 1633 of the Social Security Act (42 U.S.C. 902(a)(5), 1383, and 1383b).

2. Section 416.1442 is amended by revising paragraph (g), to read as follows:

##### § 416.1442 Prehearing proceedings and decisions by attorney advisors.

\* \* \* \* \*

(g) *Sunset provision.* The provisions of this section will no longer be effective on April 1, 1999, unless they are extended by the Commissioner of Social Security by publication of a final rule in the **Federal Register**.

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#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Parts 868, 884, and 890

[Docket No. 94N-0418]

##### Medical Devices; Retention of Three Preamendment Class III Devices in Class III

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is retaining the following three preamendments class III devices in class III: Lung water monitor, powered vaginal muscle stimulator for therapeutic use, and stair-climbing wheelchair. The agency is taking this action 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.

**EFFECTIVE DATE:** July 30, 1998.

##### 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

In the **Federal Register** of June 18, 1997 (62 FR 33044), FDA issued a proposed rule to retain the lung water monitor, the powered vaginal muscle stimulator for therapeutic use, and the stair-climbing wheelchair in class III. This proposed retention in class III was based on a lack of information submitted in response to the section 515(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(i)) order to determine whether or not special controls could be established to reasonably assure the safety and effectiveness of these devices.

Interested persons were given until September 16, 1997, to comment on the proposed rule. During the comment period, FDA received no comments on the proposed rule.

##### II. FDA's Conclusion

FDA has concluded that insufficient information exists to establish special controls to provide reasonable assurance of the safety and effectiveness of the lung water monitor, the powered vaginal muscle stimulator for therapeutic use, and the stair-climbing wheelchair and/or that these devices present a potential unreasonable risk of illness or injury.

##### III. 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.

#### IV. Analysis of Impacts

FDA has examined the impacts of the final 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 final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final 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, and because this rule retains these devices as previously classified, the agency certifies that this 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.

#### V. Paperwork Reduction Act of 1995

This 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.

This final rule is issued under sections 513, 515(i), and 701(a) of the act (21 U.S.C. 360c, 360e(i), and 371(a)) and under authority of the Commissioner of Food and Drugs.

Dated: June 17, 1998.

#### D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 98-17290 Filed 6-29-98; 8:45 am]

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#### DEPARTMENT OF THE TREASURY

##### Internal Revenue Service

##### 26 CFR Parts 1 and 301

[TD 8772]

RIN 1545-AU08

##### Magnetic Media Filing Requirements for Information Returns

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final and temporary regulations.

**SUMMARY:** This document contains final and temporary regulations relating to the requirements for filing information returns on magnetic media or in other machine-readable form under section 6011(e) of the Internal Revenue Code (Code). These regulations affect persons filing information returns. These regulations prescribe magnetic media filing requirements for employers filing wage and tax statements for employees in Puerto Rico, U.S. Virgin Islands, Guam, and American Samoa. In addition, these regulations provide taxpayers with the guidance to comply with the changes made to the Code and to the administrative practices with respect to filing on magnetic media or in other machine-readable form.

**DATES:** *Effective date:* These regulations are effective June 30, 1998.

*Applicability date:* These regulations apply to information returns required to be filed on or after January 1, 1997.

**FOR FURTHER INFORMATION CONTACT:** Donna Joy Welch, (202) 622-4910 (not a toll-free call), if the inquiry relates to provisions of these regulations. For further information, see the telephone numbers listed at the beginning of **SUPPLEMENTARY INFORMATION**.

**SUPPLEMENTARY INFORMATION:** If the inquiry relates to magnetic media filing and magnetic media specifications for Form W-2, Form 499R-2/W-2PR, Form W-2VI, Form W-2GU, and Form W-2AS, persons residing in the following locations should contact the corresponding Social Security Administration office (not a toll-free call):

Alabama (404) 562-1314 (Atlanta),  
Alaska (206) 615-2125 (Seattle),  
American Samoa (415) 744-4559 (San Francisco),  
Arizona (415) 744-4559 (San Francisco),  
Arkansas (501) 324-5466 (Little Rock),  
California (415) 744-4559 (San Francisco),  
Colorado (303) 844-2364 (Denver),  
Connecticut (617) 565-2895 (Boston),  
Delaware (215) 597-4632 (Philadelphia),

District of Columbia (215) 597-4632 (Philadelphia),  
Florida (404) 562-1314 (Atlanta),  
Georgia (404) 562-1314 (Atlanta),  
Guam (415) 744-4559 (San Francisco),  
Hawaii (415) 744-4559 (San Francisco),  
Idaho (206) 615-2125 (Seattle),  
Illinois (312) 575-4244 (Chicago),  
Indiana (312) 575-4244 (Chicago),  
Iowa (816) 936-5649 (Kansas City),  
Kansas (816) 936-5649 (Kansas City),  
Kentucky (404) 562-1314 (Atlanta),  
Louisiana (504) 389-0426 (Baton Rouge),  
Maine (617) 565-2895 (Boston),  
Maryland (215) 597-4632 (Philadelphia),  
Massachusetts (617) 565-2895 (Boston),  
Michigan (312) 575-4244 (Chicago),  
Minnesota (312) 575-4244 (Chicago),  
Mississippi (404) 562-1314 (Atlanta),  
Missouri (816) 936-5649 (Kansas City),  
Montana (303) 844-2364 (Denver),  
Nebraska (816) 936-5649 (Kansas City),  
Nevada (415) 744-4559 (San Francisco),  
New Hampshire (617) 565-2895 (Boston),  
New Jersey (212) 264-5643 (New York),  
New Mexico (505) 262-6048 (Albuquerque),  
New York (212) 264-5643 (New York),  
North Carolina (404) 562-1314 (Atlanta),  
North Dakota (303) 844-2364 (Denver),  
Ohio (312) 575-4244 (Chicago),  
Oklahoma (405) 951-3007 (Oklahoma City),  
Oregon (206) 615-2125 (Seattle),  
Pennsylvania (215) 597-4632 (Philadelphia),  
Puerto Rico (787) 766-5574 (San Juan),  
Rhode Island (617) 565-2895 (Boston),  
South Carolina (404) 562-1314 (Atlanta),  
South Dakota (303) 844-2364 (Denver),  
Tennessee (404) 562-1314 (Atlanta),  
Texas-Central/South (210) 229-6433 (San Antonio),  
Texas-Dallas County (214) 767-6777 (Dallas),  
Texas-North (817) 978-3123 (Forth Worth),  
Texas-Southeast (713) 718-3015 (Houston),  
Texas-West (505) 262-6048 (Albuquerque),  
Utah (303) 844-2364 (Denver),  
Vermont (617) 565-2895 (Boston),  
Virgin Islands (787) 766-5574 (San Juan),  
Virginia (215) 597-4632 (Philadelphia),  
Washington (206) 615-2125 (Seattle),  
West Virginia (215) 597-4632 (Philadelphia),  
Wisconsin (312) 575-4244 (Chicago),  
and  
Wyoming (303) 844-2364 (Denver).

If the inquiry relates to either the waiver procedure for all forms described