(b) *Waiver requests.* Any person or entity may file a written waiver request with the Finance Board.

(1) *Procedure.* Any request for a waiver shall be filed with the Executive Secretary, Federal Housing Finance Board, 1777 F Street, N.W., Washington, D.C. 20006, and, if from a Bank member institution, with the appropriate Bank.

(2) *Documentation.* A waiver request shall include the following:

(i) A detailed statement of facts, including the provisions of this chapter to which the request relates, the participants in the proposed transaction, and the reasons for the request; and

(ii) An analysis of each legal issue raised.

Dated: November 7, 1996.

By the Board of Directors of the Federal Housing Finance Board.

Bruce A. Morrison,

Chairman.

[FR Doc. 96–31039 Filed 12–5–96; 8:45 am]

BILLING CODE 6725–01–P

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4]

RIN 0960–AE60

Federal Old-Age, Survivors and Disability Insurance; Determining Disability and Blindness; Extension of Expiration Date for Growth Impairment Listings

AGENCY: Social Security Administration.

ACTION: Final rule.

SUMMARY: The Social Security Administration (SSA) adjudicates claims at the third step of its sequential process for evaluating disability using the Listings of Impairments under the Social Security and supplemental security income (SSI) programs. This rule extends until December 7, 1998 the date on which the growth impairment listings contained in Part B of the listings will no longer be effective. We have made no revisions to the medical criteria in the growth impairment listings; they remain the same as they now appear in the Code of Federal Regulations. This extension will ensure that we continue to have medical evaluation criteria in the listings to adjudicate claims for disability based on growth impairments in individuals under age 18 at step three of our sequential evaluation process.

EFFECTIVE DATE: This regulation is effective December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Regarding this Federal Register document—Robert J. Augustine, Legal Assistant, Division of Regulations and Rulings, Social Security Administration, 6401 Security Boulevard, Baltimore, MD 21235, (410) 965–1758; regarding eligibility or filing for benefits—our national toll-free number, 1–800–772–1213.

SUPPLEMENTARY INFORMATION: On December 6, 1985, we published revised listings, including the growth impairment listings (50 FR 50068), in appendix 1 (Listing of Impairments) to subpart P of part 404. We use the listings at the third step of the sequential evaluation process to evaluate claims filed by adults and individuals under age 18 for benefits based on disability under the Social Security and SSI programs. The listings are divided into part A and part B. We use the criteria in part A to evaluate impairments of adults. We use the criteria in part B first to evaluate impairments of individuals under age 18. If those criteria do not apply, then the medical criteria in part A will be used. The growth impairment listings apply only to individuals under age 18 and are contained in Part B of the listings.

When we published the revised listings in 1985, we indicated that medical advances in disability evaluation and treatment and program experience would require that the listings be periodically reviewed and updated. Accordingly, we established a date of December 6, 1993, for the growth impairment listings in part B, on which those listings would no longer be effective unless extended by the Secretary of Health and Human Services (the Secretary) or revised and promulgated again. Subsequently, the Secretary issued a final rule on December 6, 1993 (58 FR 64121), extending the date on which the growth impairment listings in part B would no longer be effective to December 6, 1996. Section 102 of the Social Security Independence and Program Improvements Act of 1994, Public Law 103–296 transferred the responsibility for administering the Social Security and SSI programs from the Secretary to the Commissioner of Social Security (the Commissioner).

In this final rule, we are extending for two years, to December 7, 1998, the date on which the growth impairment listings will no longer be effective. We believe that the requirements in these listings are still valid for our program purposes. Specifically, if we find that an individual has an impairment that meets the statutory duration requirement and also meets or is medically or functionally equivalent in severity to an impairment in the listings, we will find that the individual is disabled at the third step of the sequential process for evaluating disability.

Regulatory Procedures

Pursuant to section 702(a)(5) of the Social Security Act, 42 U.S.C. 902(a)(5), as amended by section 102 of Public Law 103–296, SSA follows the Administrative Procedure Act (APA) rulemaking procedures specified in 5 U.S.C. 553 in the development of its regulations. The APA provides exceptions to its notice and public comment procedures when an agency finds there is good cause for dispensing with such procedures on the basis that they are impracticable, unnecessary, or contrary to the public interest. We have determined that, under 5 U.S.C. 553(b)(B), good cause exists for dispensing with the notice and public comment procedures in this case. Good cause exists because this regulation only extends the date on which the growth impairment listings will no longer be effective. It makes no substantive changes to the listings. The current regulations expressly provide that the listings may be extended, as well as revised and promulgated again. Therefore, opportunity for prior comment is unnecessary, and we are issuing this regulation as a final rule.

In addition, we find good cause for dispensing with the 30-day delay in the effective date of a substantive rule, provided for by 5 U.S.C. 553(d). As explained above, we are not making any substantive changes in the growth impairment listings. However, without an extension of the expiration date for the growth impairment listings, we will lack regulatory guidelines for assessing growth impairments at the third step of the sequential evaluation processes after the current expiration date of the listings. In order to ensure that we continue to have regulatory criteria for assessing these impairments under the listings, we find that it is in the public interest to make this rule effective upon publication.

Executive Order 12866

We have consulted with the Office of Management and Budget (OMB) and determined that this rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review.

Regulatory Flexibility Act

We certify that this regulation will not have a significant economic impact on a substantial number of small entities.

Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

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

Dated: December 2, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

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

Subpart P—[Amended]

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

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 1 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): December 7, 1998.

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[FR Doc. 96–31037 Filed 12–5–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket Number 94P–0443]

Medical Devices; Reclassification of Acupuncture Needles for the Practice of Acupuncture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III (premarket approval) into class II (special controls). FDA is also announcing it has issued an order in the form of a letter to the Acupuncture Coalition reclassifiying acupuncture needles. This action is in response to petitions filed by the Acupuncture Coalition and in keeping with, but not dependent upon, the recommendation of FDA's Anesthesiology Devices Advisory Panel (the Panel). This action is being taken because the agency believes that there is sufficient information to establish that special controls will provide reasonable assurance of the safety and effectiveness of acupuncture needles.

EFFECTIVE DATE: December 6, 1996.

FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: On December 6, 1995, FDA filed reclassification petitions from the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France; Seirin-Kasei (Mfg.), Japan; Ito Co., Japan; and Ido-No-Nippon-Sha, Japan, requesting reclassification of acupuncture needles from class III to class II. On March 29, 1996, FDA issued an order (Ref. 1) in the form of a letter, to the petitioners reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III to class II. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and § 860.134 (21 CFR 860.134) provide for the reclassification by order of devices not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments.

Under section 513(f)(2) of the act and § 860.134, FDA may refer a reclassification petition to an appropriate panel. Although FDA did not refer the reclassification petitions submitted by the Acupuncture Coalition to a panel, the Anesthesiology Devices Advisory Panel (the Panel) had previously considered the classification of acupuncture needles and other acupuncture devices and recommended that acupuncture needles be placed into class II, as reported in the Federal Register of November 2, 1979 (44 FR 63292 at 63299) (Ref. 2). The supplemental data sheet completed by the Panel on November 30, 1976 (Ref. 3), listed sepsis, excessive trauma, and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use. FDA's decision to reclassify acupuncture needles as class II is in keeping with, but not dependent upon, the recommendation of the Panel.

FDA determined that acupuncture needles could safely be reclassified from class III to class II with the implementation of special controls. Acupuncture needles are devices intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

The order identified the special controls needed to provide reasonable assurance of the safety and effectiveness of acupuncture needles. Those special controls are in compliance with: (1) Labeling provisions for single use only and the prescription statement in § 801.109 (21 CFR 801.109) (restriction to use by or on the order of qualified practitioners as determined by the States), (2) device material biocompatibility, and (3) device sterility. FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States. Guidance on the type of information needed to support biocompatibility and sterility of