

reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Airbus Industrie, 1 Rond Point Maurice Bellonte, 31707 Blagnac Cedex, France. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 4: The subject of this AD is addressed in French airworthiness directives 97-017-043(B)R2, dated June 18, 1997, as revised by ERRATUM, dated July 2, 1997; and 97-018-059(B)R2, dated June 18, 1997, as revised by ERRATUM, dated July 2, 1997.

(e) This amendment becomes effective on February 17, 1998.

Issued in Renton, Washington, on January 23, 1998.

Stewart R. Miller,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98-2286 Filed 1-29-98; 8:45 am]

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SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regulations No. 4]

RIN 0960-AE80

Federal Old-Age, Survivors and Disability Insurance; Determining Disability and Blindness; Extension of Expiration Date for the Cardiovascular Body System 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 Listing of Impairments (the listings) under the Social Security and supplemental security income (SSI) programs. This rule extends the date on which the cardiovascular body system listings will no longer be effective. We have made no revisions to the medical criteria in these 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 impairments in the cardiovascular body system at step three of our sequential evaluation process.

EFFECTIVE DATE: This regulation is effective January 30, 1998.

FOR FURTHER INFORMATION CONTACT: Regarding this **Federal Register** document—Richard M. Bresnick, Legal Assistant, 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: We use the listings in appendix 1 (Listing of Impairments) to subpart P of part 404 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 parts A and 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.

When we published revised listings in 1985 and subsequently, 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 dates ranging from 3 to 8 years on which the various body system listings would no longer be effective unless extended by the Secretary of Health and Human Services or revised and promulgated again. Effective March 31, 1995, the authority to issue regulations was transferred to the Commissioner of Social Security by section 102 of Public Law 103-296, the Social Security Independence and Program Improvements Act of 1994.

In this final rule, we are extending the date on which the cardiovascular body system listings (4.00 and 104.00) will no longer be effective to February 10, 2000.

We last published final rules for the cardiovascular body system listings on February 10, 1994 (59 FR 6468).

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 equivalent in severity to an impairment in the listings or functionally equivalent to the listings in SSI claims based on disability filed by individuals under age 18, we will find that the individual is disabled at the third step of the sequential evaluation process.

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 cardiovascular body system 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 these body system listings. However, without an extension of the expiration date for these listings, we will lack regulatory guidelines for assessing impairments in the cardiovascular body system 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 cardiovascular 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 the Regulatory Flexibility Act, as amended, 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: January 20, 1998.

Kenneth S. Apfel,

Commissioner of Social Security.

For the reasons set forth in the preamble, chapter III, part 404, subpart P 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)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Appendix 1 to subpart P of part 404 is amended by revising item 5 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

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5. Cardiovascular System (4.00 and 104.00): February 10, 2000.

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[FR Doc. 98–2276 Filed 1–29–98; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 97N–0133]

Revising the Announcement Procedures for Approvals and Denials of Premarket Approval Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to revise the premarket approval application (PMA) announcement procedure. FDA is discontinuing the

publication of individual PMA approvals and denials in the **Federal Register**. Instead, the agency will announce approvals and denials of PMA's on the Internet. FDA will make the summaries of safety and effectiveness available through the Internet and by placing them in FDA's Dockets Management Branch. FDA will publish in the **Federal Register** for each quarter a list of the approvals and denials announced in that quarter. FDA is taking this action in order to expedite the availability of this information.

EFFECTIVE DATE: March 2, 1998.

FOR FURTHER INFORMATION CONTACT: Joseph M. Sheehan, Center for Devices and Radiological Health (HFZ–215), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–827–2974.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 12, 1980 (45 FR 81769 at 81772), FDA prescribed the contents of a PMA and the criteria for approving, disapproving, or withdrawing approval of a PMA. FDA acknowledged that, although the statute does not require it to publish the approval of a PMA in the **Federal Register**, section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) permits an interested person to obtain review of an approved PMA. Consequently, FDA proposed to announce approval of any PMA in the **Federal Register** and to include in the announcement notice of opportunity to petition for administrative review under section 515(g) of the act. (See 45 FR 81769 at 81772 and 81776). FDA also proposed to publish notice of any denial of approval or proposed withdrawal of approval of any PMA in the **Federal Register** and to include in the announcement notice of opportunity for administrative review under section 515(g) of the act. (See 45 FR 81769 at 81773 and 81777.) Subsequently, in the **Federal Register** of July 22, 1986 (51 FR 26342), FDA issued a final rule providing, among other things, that notice of approval of a PMA, notice of an order denying approval of a PMA, and notice of an order withdrawing approval of a PMA will be published in the **Federal Register**. (See 21 CFR 814.44(d), 814.45(d), and 814.46(e).) In the **Federal Register** of June 27, 1997 (62 FR 34680), FDA issued a proposed rule to revise the PMA announcement procedure by discontinuing publication of PMA approvals and denials in the **Federal Register** and, instead, announcing them on the Internet. Interested persons were

given until September 25, 1997, to comment on the proposed regulation. FDA received two comments supporting the proposal, one from an in vitro diagnostic manufacturer and the other from a dental association.

II. Summary of the Final Rule

FDA is discontinuing publication of individual PMA approvals and denials in the **Federal Register**. Instead, FDA will notify the public of PMA approvals and denials by posting them on FDA's home page on the Internet (<http://www.fda.gov>), by placing the summaries of safety and effectiveness on the Internet and in FDA's Dockets Management Branch, and by publishing in the **Federal Register** after each quarter a list of the PMA approvals and denials announced in that quarter.

FDA believes that this procedure will expedite public notification of these actions because announcements can be placed on the Internet more quickly than they can be published in the **Federal Register**, and FDA believes that the Internet is accessible to more people than is the **Federal Register**.

In accordance with section 515(d)(3) of the act, notification of an order approving, denying, or withdrawing approval of a PMA will continue to include a notice of opportunity to request review of the order under section 515 (g) of the act. The 30-day period for requesting reconsideration of an FDA action under § 10.33(b) (21 CFR 10.33(b)) for notices announcing approval of a PMA will begin on the day the notice is placed on the Internet. Section 10.33(b) provides that FDA may, for good cause, extend this 30-day period. Reconsideration of a denial or withdrawal of approval of a PMA may be sought only by the applicant, in these cases, the 30-day period will begin when the applicant is notified by FDA in writing of its decision.

III. 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.

IV. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory