of the three items listed in paragraph (c)(2)(i) of this section was greater than \$7 million (positive or negative), at any time during the affiliate's 1999 fiscal year.

(iii) Notwithstanding paragraphs (c)(2)(i) and (c)(2)(ii) of this section, a Form BE–10B(LF) or (SF) must be filed for a foreign affiliate of the U.S. Reporter that owns another nonexempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt, i.e., a Form BE–10B(LF), (SF), or BANK must be filed for all affiliates upward in a chain of ownership.

- (d) Forms for U.S. Reporters and foreign affiliates that are banks or bank holding companies. (1) For purposes of the BE-10 survey, "banking" covers a business entity engaged in deposit banking or closely related functions, including commercial banks, Edge Act corporations engaged in international or foreign banking, foreign branches and agencies of U.S. banks whether or not they accept deposits abroad, savings and loans, savings banks, and bank holding companies, i.e., holding companies for which over 50 percent of their total income is from banks that they hold. If the bank or bank holding company is part of a consolidated business enterprise and the gross operating revenues from nonbanking activities of this consolidated entity are more than 50 percent of its total revenues, then the consolidated entity is deemed not to be a bank even if banking revenues make up the largest single source of all revenues. (Activities of subsidiaries of a bank or bank holding company that may not be banks but that provide support to the bank parent company, such as real estate subsidiaries set up to hold the office buildings occupied by the bank parent company, are considered bank activities.)
- (2) Form BE-10A BANK (Report for a U.S. Reporter that is a bank). A BE-10A BANK report must be completed by a U.S. Reporter that is a bank. For purposes of filing Form BE-10A BANK, the U.S. Reporter is deemed to be the fully consolidated U.S. domestic business enterprise and all required data on the form shall be for the fully consolidated domestic entity.
- (i) If a U.S. bank had any foreign affiliates at any time during its 1999 fiscal year, whether a bank or nonbank and whether held directly or indirectly, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$7 million (positive or negative) at any time during the affiliate's 1999 fiscal year, the U.S. Reporter must file a Form

BE–10A BANK and, as applicable, a BE–10A BANK SUPPLEMENT listing each, if any, foreign affiliate, whether bank or nonbank, that is exempt from being reported on Form BE–10B (SF), or BE–10B BANK. It must also file a Form BE–10B (SF) for each nonexempt nonbank foreign affiliate and a Form BE–10B BANK for each nonexempt bank foreign affiliate.

- (ii) If the U.S. bank Reporter had no foreign affiliates for which any one of the three items listed in paragraph (d)(2)(i) of this section was greater than \$7 million (positive or negative) at any time during the affiliate's 1999 fiscal year, the U.S. Reporter must file a Form BE–10A BANK and a BE–10A BANK SUPPLEMENT, listing all foreign affiliates exempt from being reported on Form BE–10B (SF) or BE–10 BANK.
- (3) Form BE-10B BANK (Report for a foreign affiliate that is a bank). (i) A BE-10B BANK report must be filed for each foreign bank affiliate of a bank or nonbank U.S. Reporter, whether directly or indirectly held, for which any one of the three items—total assets, sales or gross operating revenues excluding sales taxes, or net income after provision for foreign income taxes—was greater than \$7 million (positive or negative) at any time during the affiliate's 1999 fiscal year.
- (ii) Notwithstanding paragraph (d)(3)(i) of this section, a Form BE-10B BANK must be filed for a foreign bank affiliate of the U.S. Reporter that owns another nonexempt foreign affiliate of that U.S. Reporter, even if the foreign affiliate parent is otherwise exempt, i.e., a Form BE-10B (LF), (SF), or BANK must be filed for all affiliates upward in a chain of ownership. However, a Form BE-10B BANK is not required to be filed for a foreign bank affiliate in which the U.S. Reporter holds only an indirect ownership interest of 50 percent or less and that does not own a reportable nonbank foreign affiliate, but the indirectly owned bank affiliate must be listed on the BE-10A BANK SUPPLEMENT.
- (e) Due date. A fully completed and certified BE–10 report comprising Form BE–10A or 10A BANK, BE–10A SUPPLEMENT (as required), and Form(s) BE–10B (LF), (SF), or BANK (as required) is due to be filed with BEA not later than May 31, 2000 for those U.S. Reporters filing fewer than 50, and June 30, 2000 for those U.S. Reporters filing 50 or more, Forms BE–10B (LF), (SF), or BANK.

[FR Doc. 99–31412 Filed 12–2–99; 8:45 am] BILLING CODE 3510–06–M

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Regs. No. 4] RIN 0960-AF15

Extension of Expiration Dates for Several Body System Listings

AGENCY: Social Security Administration

(SSA).

ACTION: Final rule.

SUMMARY: SSA adjudicates claims at the third step of its sequential evaluation process for evaluating disability using the Listing of Impairments (the Listings) under the Social Security and Supplemental Security Income (SSI) programs. This final rule extends the dates on which several 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. These extensions will ensure that we continue to have medical evaluation criteria in these listings to adjudicate claims for disability based on impairments in these body systems at step three of our sequential evaluation process.

EFFECTIVE DATE: This final regulation is effective December 3, 1999.

FOR FURTHER INFORMATION CONTACT:

Deborah Barnes, Social Insurance Specialist, Office of Disability, Social Security Administration, 3–A–9 Operations Building, 6401 Security Boulevard, Baltimore, MD 21235–6401, (410) 965–4171 or TTY (410) 966–5609. For information on eligibility, claiming benefits, or coverage of earnings, call our national toll-free number, 1–800– 772–1213 or TTY 1–800–325–0778.

SUPPLEMENTARY INFORMATION: We use the Listings in appendix 1 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 the 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 they 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 dates on which several body system listings will no longer be effective to July 2, 2001. These body systems are: Cardiovascular System (4.00 and 104.00).

Digestive System (5.00 and 105.00). Genito-Urinary System (6.00 and 106.00).

We last extended the dates on which these body system listings would no longer be effective in final rules published as follows:

June 5, 1997 (62 FR 30746): Digestive System and Genito-Urinary System. January 30, 1998 (63 FR 4570): Cardiovascular System.

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 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 and also meets the statutory duration requirement, we will find that the individual is disabled at the third step of the sequential evaluation process. We are extending these dates because we do not expect to develop revised listings criteria for these body systems by the expiration dates currently shown in the regulations. However, we are reviewing the listings and we plan to publish proposed and final rules over the course of the next two years.

Regulatory Procedures

Justification for Final Rule

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 these body system listings will no longer be effective. It makes no substantive changes to those listings. The current regulations expressly provide that 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 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 dates for these listings, we will lack regulatory guidelines for assessing impairments in these body systems at the third step of the sequential evaluation process after the current expiration dates of these listings. In order to ensure that we continue to have regulatory criteria for assessing impairments under these 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 final rule does not meet the criteria for a significant regulatory action under Executive Order 12866. Thus, it was not subject to OMB review. We have also determined that this final rule meets the plain language requirement of Executive Order 12866 and the President's memorandum of June 1, 1998 (63 FR 31885).

Regulatory Flexibility Act

We certify that this final 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 final 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: November 24, 1999.

Kenneth S. Apfel.

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)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189.

2. Appendix 1 to subpart P of part 404 is amended by revising items 5, 6, and 7 of the introductory text before Part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

- 5. Cardiovascular System (4.00 and 104.00): July 2, 2001.
- 6. Digestive System (5.00 and 105.00): July 2, 2001.
- 7. Genito-Urinary System (6.00 and 106.00): July 2, 2001.

[FR Doc. 99–31322 Filed 12–2–99; 8:45 am]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 203 and 205

[Docket Nos. 92N-0297 and 88N-0258] RIN 0910-AA08

Prescription Drug Marketing Act of 1987; Prescription Drug Amendments of 1992; Policies, Requirements, and Administrative Procedures

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final