Thereafter, on December 6, 1993 (58 FR 64121), the expiration date of the musculoskeletal system listings in both parts A and B was extended, as were the expiration dates for several other body system listings. That rule provided that the musculoskeletal system listings would no longer be effective on June 6, 1996.

Also, we published a notice of proposed rulemaking (NPRM) on December 21, 1993 (58 FR 67574) that included proposed revisions to these listings. We will publish any changes to the listings based on that NPRM in a subsequent final rule.

In this final regulation, we are extending for one year, to June 6, 1997, the date on which the musculoskeletal system 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 equivalent in severity to an impairment in the listings, we will find that the individual is disabled without completing the remaining steps of the sequential evaluation process. We do not use the listings to find that an individual is not disabled. Individuals whose impairments do not meet or equal the criteria of the listings receive individualized assessments at the subsequent steps 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 musculoskeletal 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 the listings. However, without an extension of the expiration date for the musculoskeletal system listings, we will lack regulatory guidelines for assessing musculoskeletal system 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: May 20, 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 2 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

2. Musculoskeletal System (1.00 and 101.00): June 6, 1997.

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[FR Doc. 96–13882 Filed 6–3–96; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committee; Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and the function of the Fertility and Maternal Health Drugs Advisory Committee. This action is being taken to more accurately describe this committee.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Fertility and Maternal Health Drugs Advisory Committee has been changed. After reestablishment of this committee, on March 23, 1978, the agency decided that the name ''Advisory Committee for Reproductive Health Drugs'' would more accurately describe the subject areas for which the committee is

responsible. The mandate of the committee has expanded significantly in recent years to include drugs for menopausal women and drugs used in the practice of andrology. The change is consistent with the growing use of this term by specialists in the field of reproductive health, which includes obstetrics, gynecology, endocrinology, andrology, epidemiology, and related specialties. The committee reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

The Fertility and Maternal Health Drugs Advisory Committee's name was changed in the charter renewal dated March 23, 1996. In this document, FDA is hereby formally changing the name and the function of the committee by revising 21 CFR 14.100(c)(9).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading of paragraph (c)(9) and paragraph (c)(9)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(9) *Advisory Committee for Reproductive Health Drugs.*

* * * * *

(ii) Function: Reviews and evaluates data on the safety and effectiveness of marketed and investigational human drugs for use in the practice of obstetrics, gynecology, and related specialties.

* * * * *

Dated: May 28, 1996.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 96–13978 Filed 6–3–96; 8:45 am]

BILLING CODE 4160–01–F

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21 CFR Part 14

Standing Advisory Committees; Change of Name and Function

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and the function of the Generic Drugs Advisory Committee to the Advisory Committee for Pharmaceutical Science. This action is being taken to more accurately describe this committee.

EFFECTIVE DATE: June 4, 1996.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA–306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2765.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Generic Drugs Advisory Committee has been changed. After establishment of this committee, on January 22, 1990, the agency decided that the name ''Advisory Committee for Pharmaceutical Science'' would more accurately describe the committee. The Committee reviews primary scientific issues dealing with pharmaceutical science including testing, research, biopharmaceutics, pharmacology, and new chemistry. The Committee also gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases. Therefore, the agency feels the name change will more accurately describe this Committee to the public. In the Federal Register of February 21, 1996 (61 FR 6644 at 6645), FDA published a notice that indicated that the name of the Generic Drugs Advisory Committee had been changed in the charter renewal dated January 22, 1996. In this document, FDA is hereby formally changing the name and function of the committee by revising 21 CFR 14.100(c)(16).

Publication of this final rule constitutes a final action on this change under the Administrative Procedure Act. Under 5 U.S.C. 553(b)(3)(B) and (d) and under 21 CFR 10.40(d) and (e), the agency finds good cause to dispense with notice and public procedure, and to proceed to an immediately effective regulation. Such notice and procedures are unnecessary and are not in the public interest, because the final rule is merely a clarifying amendment to existing regulations and when effective will reflect the current committee charter.

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: Secs. 201–903 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321–394; 21 U.S.C. 41–50, 141–149, 467f, 679, 821, 1034; secs. 2, 351, 354, 361 of the Public Health Service Act (42 U.S.C. 201, 262, 263b, 264); secs. 2–12 of the Fair Packaging and Labeling Act (15 U.S.C. 1451–1461); 5 U.S.C. App. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by revising the heading for paragraph (c)(16) and paragraph (c)(16)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(16) *Advisory Committee for Pharmaceutical Science.*

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(ii) Function: Gives advice on scientific and technical issues concerning the safety and effectiveness of human generic drug products for use in the treatment of a broad spectrum of human diseases.

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