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.*

* * * * *

(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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