

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.

DDM
Display Date 3-2-07
Publication Date 3-5-07
Certifier D. Hawkins

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name and function of the Advisory Committee for Pharmaceutical Science. This action is being taken to reflect changes made to the charter for this advisory committee.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Theresa Green, Committee Management Officer (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1220.

SUPPLEMENTARY INFORMATION: FDA is announcing that the name of the Advisory Committee for Pharmaceutical Science, which was established on January 22, 1990, has been changed. The name Advisory Committee for Pharmaceutical Science and Clinical Pharmacology more accurately describes the subject areas for which the committee is responsible. The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which FDA has regulatory responsibility, and make appropriate recommendations to the

Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development

FDA is revising § 14.100(c)(16) (21 CFR 14.100(c)(16)) to reflect these changes. In this document, FDA is hereby formally changing the name and the function of the committee by revising § 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)(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 codifying the new name and expanded function of the advisory committee to 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: 5 U.S.C. App. 2; 15 U.S.C. 1451-1461, 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155.

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

§ 14.100 List of standing advisory committees.

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(c) * * *

*J.P. Dredia
Wingate
07/12*

(16) Advisory Committee for Pharmaceutical Science and Clinical Pharmacology.

(i) * * *

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(ii) Function: The committee shall provide advice on scientific, clinical and technical issues related to safety and effectiveness of drug products for use in the treatment of a broad spectrum of human diseases, the quality characteristics which such drugs purport or are represented to have and as required, any other product for which the Food and Drug Administration has regulatory responsibility, and make appropriate recommendations to the Commissioner of Food and Drugs. The Committee may also review agency sponsored intramural and extramural biomedical research programs in support of FDA's drug regulatory responsibilities and its critical path initiatives related to improving the efficacy and safety of drugs and improving the efficiency of drug development.

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Dated: 2/26/07
February 26, 2007.



Randall W. Lutter,
Associate Commissioner for Policy and Planning.

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Nawn P. Hawkins