Dated: July 16, 2009.

Matthew S. Borman,

Acting Assistant Secretary for Export Administration.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA–2009–N–0310]

Advisory Committee; Risk Communication Advisory Committee; Termination and Recharter

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination and the recharter of the Risk Communication Advisory Committee (the committee). These actions are needed to implement the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Food and Drug Administration Amendments Act of 2007, to change the committee from a discretionary to a statutory committee. This document also amends the agency's regulations which list advisory committees to reflect that the Risk Communication Advisory Committee has been rechartered and to revise the function statement.

DATES: This rule is effective July 21, 2009. The committee is being rechartered and the new charter will remain in effect until amended or terminated by the Commissioner of Food and Drugs (the Commissioner) or designee.

FOR FURTHER INFORMATION CONTACT: Lee Zwanziger, Office of Policy and Planning (HFP–1), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–2895, FAX: 301–827–4050, or e-mail: *Lee.Zwanziger@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Public Law 92–463 (5 U.S.C. app. 2)); section 904 of the act (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Public Law 101–635); and 21 CFR 14.40(b), FDA is announcing the termination and the recharter of the committee by the Commissioner. The committee advises the Commissioner and designees on methods to effectively communicate risks associated with products regulated by FDA, and in discharging responsibilities as they relate to helping ensure safe and effective drugs for human use and any other product for which FDA has regulatory responsibility. The committee also reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. In addition, the committee reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about using FDA-regulated products.

The committee will be composed of a core of 15 voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities knowledgeable in fields such as social marketing, health literacy, and other relevant areas. Members will include experts on risk communication; experts on emerging postmarket drug risks; and individuals knowledgeable about and experienced in the work of patient, consumer, and health professional organizations. Members will be invited to serve for overlapping terms of up to 4 years. Almost all non-Federal members of this committee serve as Special Government Employees. Some members will be selected to provide experiential insight on the communication needs of the various groups who use FDA-regulated products. The latter may include patients and patients' family members; health professionals; communicators in health, medicine, and science; and persons affiliated with consumer, specific disease, or patient safety advocacy groups. The Commissioner or designee shall also have the authority to select from a group of individuals nominated by industry to serve temporarily as nonvoting members who are identified with industry interests. The number of temporary members selected for a particular meeting will depend on the meeting topic(s).

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 comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely amends the information in § 14.100 (21 CFR 14.100) to reflect the rechartering of the committee and to revise the function statement.

Therefore, the agency is amending § 14.100(a)(4)(i) and (a)(4)(ii) as set forth in the regulatory text of this document.

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 paragraphs (a)(4)(i) and (a)(4)(ii) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(a) * * *

(4) * * *

(i) Date Rechartered: July 9, 2009.

(ii) Function: The committee reviews and evaluates strategies and programs designed to communicate with the public about the risks and benefits of FDA-regulated products so as to facilitate optimal use of these products. The committee also reviews and evaluates research relevant to such communication to the public by both FDA and other entities. It also facilitates interactively sharing risk and benefit information with the public to enable people to make informed independent judgments about use of FDA-regulated products.

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Dated: July 10, 2009.

Randall W. Lutter,

Deputy Commissioner for Policy.

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