



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2016-N-0001]

Advisory Committee; Transmissible Spongiform Encephalopathies Advisory Committee;
Termination

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the termination of the Transmissible Spongiform Encephalopathies Advisory Committee. This document removes the Transmissible Spongiform Encephalopathies Advisory Committee from the Agency's list of standing advisory committees.

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

FOR FURTHER INFORMATION CONTACT: Bryan Emery, Division of Scientific Advisors and Consultants, Food and Drug Administration, 10903 New Hampshire Ave., Bldg.71, rm. 6132, Silver Spring, MD 20993-0002, 240-402-8054, FAX: 301-595-1307, or bryan.emery@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: The Transmissible Spongiform Encephalopathies Advisory Committee (the Committee) was established on June 9, 1995 (60 FR 31311, June 14, 1995; 21 CFR 14.100 erroneously lists the date of establishment as June 21, 1995). The Committee reviews and evaluates available scientific data concerning the safety of products that may be a risk for transmission of spongiform encephalopathies having an impact on the public

health as determined by the Commissioner of Food and Drugs. The Committee makes recommendations to the Commissioner regarding the regulation of such products. In recent years, the number of issues requiring Committee advice has declined, and the Committee has met very infrequently. Therefore, the effort and expense of maintaining this advisory committee is no longer justified. Any relevant Transmissible Spongiform Encephalopathy issues in the future could be addressed by the Agency's other advisory committees, such as the Agency's Blood Products Advisory Committee, with additional augmentation of expertise by appropriate subject matter experts serving as temporary members on the committee.

The Committee is no longer needed and will be terminated on June 9, 2016.

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 removes the name of the Transmissible Spongiform Encephalopathies Advisory Committee from the list of standing advisory committees in 21 CFR 14.100.

Therefore, the Agency is amending 21 CFR 14.100(b) 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 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.

§ 14.100 [Amended]

2. In § 14.100, redesignate paragraph (b)(5) as (b)(4) and remove paragraph (b)(6).

Dated: June 6, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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