4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

[Docket No. FDA-2013-N-0011]

Public Hearing Before a Public Advisory Committee; Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations regarding advisory committees to address minor technical changes and corrections to statutory citations. This action is editorial in nature and is intended to provide accuracy and clarity to the Agency's regulations.

DATES: This rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT:

Rosanne A. Hurwitz,

Office of Special Medical Programs,

Food and Drug Administration,

10903 New Hampshire Ave.,

Bldg. 32, rm. 5164,

Silver Spring, MD, 20993-0002,

301-796-8866,

Rosanne.Hurwitz@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

FDA is amending 21 CFR part 14 to correct minor errors and inadvertent omissions in the Code of Federal Regulations (CFR), and to delete obsolete cross-references. Minor spelling errors were inadvertently published in the CFR when the regulations were first issued. In addition, amendments to the Federal Food, Drug, and Cosmetic Act and recodification of certain sections of the Public Health Service Act resulted in changes to several of the referenced statutes.

FDA is publishing the document as a final rule under the Administrative Procedures Act (5 U.S.C. 551, et seq.). FDA has determined that good cause exists to dispense with prior notice and public comment under 5 U.S.C. 553(b)(B) and 21 CFR 10.40(e) since such notice and comment are unnecessary because this amendment to the regulations provides only technical changes to correct minor errors and inadvertent omissions in the CFR, to update obsolete terms and citations, and to delete obsolete information. These changes are nonsubstantive and only editorial in nature. In addition, FDA finds good cause to provide for this regulation to be effective immediately upon publication under 5 U.S.C. 553(d).

List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Foods, Medical Devices, Radiation protection, and Tobacco Control.

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.

Part 14 [Amended]

2. Part 14 is amended by removing the words "the Board of Tea Experts" wherever they appear; by removing the word "chairman" wherever it appears and adding in its place "Chairperson"; by removing the word "chairman's" wherever it appears and adding in its place "Chairperson's"; by removing the phrase "the act" and adding in its place "the FD&C Act"; and by removing the word "executive secretary" wherever it appears and adding in its place "Designated Federal Officer."

3. Amend § 14.1 by revising paragraphs (a) introductory text, (a)(2)(vii), and (f) to read as follows:

§ 14.1 Scope.

(a) This part governs the procedures when any of the following applies:

* * * * *

(2) * * *

(vii) Section 514(b)(5) of the FD&C Act on establishment, amendment, or revocation of a device performance standard;

* * * * *

(f) This part applies to all FDA advisory committees, except to the extent that specific statutes require otherwise for a particular committee, for example, TEPRSSC and advisory committees established under the Medical Device Amendments of 1976.

4. Amend § 14.22 by revising paragraphs (b)(6) and (i)(4) to read as follows:

§ 14.22 Meetings of an advisory committee.

* * * * *

(b) * * *

(6) The committee is concerned with matters that functionally or historically occur in some other location, e.g., the Science Advisory Board of the National Center for Toxicological Research will generally hold meetings in the Little Rock, AR, vicinity.

* * * * *

(i) * * *

(4) Notes or minutes kept or reports prepared by a committee member have no status or effect unless adopted into the official minutes or report by the committee.

5. Amend § 14.55 by removing paragraph (d); redesignating paragraphs (e) and (f) as paragraphs (d) and (e), respectively; and revising paragraph (c) and newly redesignated paragraph (d) to read as follows:

§ 14.55 Termination of advisory committees.

* * * * *

(c) TEPRSSC is a permanent statutory advisory committee established by section 358(f)(1)(A) of the Public Health Service Act, as added by the Radiation Control for Health and Safety Act of 1968, transferred to the FD&C Act (21 U.S.C. 360kk(f)(1)(A)), and is not subject to termination and renewal under paragraph (a) of this section, except that a new charter is prepared and filed at the end of each 2-year period as provided in § 14.40(c). Also, the statutory medical device classification panels established under section 513(b)(1) of the FD&C Act (21 U.S.C. 360c(b)(1)) and part 860, and the statutory medical device good manufacturing practice

advisory committees established under section 520(f)(3) of the FD&C Act (21 U.S.C. 360j(f)(3)), are specifically exempted from the normal 2-year duration period.

(d) Color additive advisory committees are required to be established under the circumstances specified in sections 721(b)(5)(C) and (D) of the FD&C Act (21 U.S.C. 379e(b)(5)(C) and (D)). A color additive advisory committee is subject to the termination and renewal requirements of the Federal Advisory Committee Act and of this part.

* * * * *

6. Amend § 14.65 by revising paragraph (a) to read as follows:

§ 14.65 Public inquiries and requests for advisory committee records.

(a) Public inquiries on general committee matters, except requests for records, are to be directed to the Committee Management Officer in the Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993.

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§ 14.120 [Amended]

7. Amend § 14.120 by removing “Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263f(f)(1)(A))” and adding in its place “Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360kk(f)(1)(A)).”

§ 14.122 [Amended]

8. Amend § 14.122 by removing “42 U.S.C. 263f” and adding in its place “21 U.S.C. 360kk” in paragraphs (a)(2) and (b).

§ 14.125 [Amended]

9. Amend § 14.125 by removing “42 U.S.C. 263f (f)(1)(A)” and adding in its place “21 U.S.C. 360kk(f)(1)(A)” in paragraph (c).

§ 14.130 [Amended]

10. Amend § 14.130 by removing “42 U.S.C. 263f (f)(1)(B)” and adding in its place “21 U.S.C. 360kk(f)(1)(B)” in paragraph (a).

Dated: March 13, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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