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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part14

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

Patient Engagement Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to add the Patient Engagement Advisory Committee.

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

FOR FURTHER INFORMATION CONTACT: Letise Williams, Office of Center Director, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, email: Letise.Williams@fda.hhs.gov, 301-796-8398.

SUPPLEMENTARY INFORMATION: The Patient Engagement Advisory Committee (the Committee) was established on October 6, 2015 (80 FR 57007, September 21, 2015).

The Committee will provide advice to the Commissioner of Food and Drugs (the Commissioner), or designee, on complex issues relating to medical devices, regulation of devices, and their use by patients.

The Committee will be composed of a core of nine voting members including the Chair. Members and the Chair are selected by the Commissioner or designee from among authorities

who are knowledgeable in areas such as clinical research, primary care patient experience, and healthcare needs of patient groups in the United States, or who are experienced in the work of patient and health professional organizations, methodologies for eliciting patient preferences, and strategies for communicating benefits, risks, and clinical outcomes to patients and research subjects. 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. The core of voting members may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests and is recommended by either a consortium of consumer-oriented organizations or other interested persons.

The function of the Committee is to provide advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

The Committee name and function were established with the Committee charter on October 6, 2015. Therefore, the Agency is amending 21 CFR 14.100 to add the Committee name and function to its current list as set forth in the regulatory text of this document.

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 is merely codifying the addition of the name and function of the Patient Engagement Advisory Committee to reflect the committee charter.

Therefore, the Agency is amending 21 CFR 14.100 to add paragraph (d)(5) 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; Pub. L. 113-54.

2. In § 14.100, add paragraph (d)(5) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(d) * * *

(5) Patient Engagement Advisory Committee.

(i) Date Established: October 6, 2015.

(ii) Function: Provides advice to the Commissioner on complex issues relating to medical devices, the regulation of devices, and their use by patients. Agency guidance and policies, clinical trial or registry design, patient preference study design, benefit-risk determinations, device labeling, unmet clinical needs, available alternatives, patient reported outcomes, and device-related quality of life or health status issues are among the topics that may be considered by the Committee. The Committee provides relevant skills and perspectives in order to improve communication of benefits, risks, and clinical outcomes, and increase integration of patient perspectives into the regulatory process for medical devices. It performs its duties by identifying new approaches, promoting innovation, recognizing unforeseen risks or barriers, and identifying unintended consequences that could result from FDA policy.

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Dated: March 15, 2016.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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