DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–3402]

Advisory Committee; National Mammography Quality Assurance Advisory Committee; Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the National Mammography Quality Assurance Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the National Mammography Quality Assurance Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until July 7, 2021.

DATES: Authority for the National Mammography Quality Assurance Advisory Committee would have expired on July 7, 2019; however, the Commissioner formally determined that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sara Anderson, Office of Management, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G616, Silver Spring, MD 20993–0002, 301–796–7047, *Sara.Anderson@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Under 41 CFR 102–3.65 and approval by the Department of Health and Human Services under 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the National Mammography Quality Assurance Advisory Committee. The committee is a non-discretionary Federal advisory committee established to provide advice to the Commissioner. The Secretary and, by delegation, the Assistant Secretary for the Office of Public Health and Science, and the Commissioner of Food and Drugs are charged with the administration of the Federal Food, Drug and Cosmetic Act and various provisions of the Public Health Service Act. The Mammography Quality Standards Act of 1992 amends the Public Health Service Act to establish national uniform quality and safety standards for mammography facilities. The National Mammography Quality Assurance Advisory Committee advises the Secretary and, by delegation, the Commissioner of Food and Drugs in discharging their responsibilities with respect to establishing a mammography facilities certification program. The Committee shall advise the Food and Drug Administration on:

(1) Developing appropriate quality standards and regulations for mammography facilities;

(2) developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;

(3) developing regulations with respect to sanctions;

(4) developing procedures for monitoring compliance with standards;

(5) establishing a mechanism to investigate consumer complaints;

(6) reporting new developments concerning breast imaging that should be considered in the oversight of mammography facilities;

(7) determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas;

(8) determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and

(9) determining the costs and benefits of compliance with these requirements.

The Committee shall consist of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. 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 shall include at least four individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least two practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include two nonvoting industry representatives who have expertise in mammography equipment. The Committee may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests.

Further information regarding the most recent charter and other information can be found at *https://www.fda.gov/advisory-committees/national-mammography-quality-assurance-advisory-committee/past-meeting-materials-national-mammography-quality-assurance-advisory-committee* or by contacting the Designated Federal Officer (see **FOR FURTHER INFORMATION CONTACT**). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app.). For general information related to FDA advisory committees, please visit us at *https://www.fda.gov/advisory-committees.*

Dated: August 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–D–0530]

Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on requests for feedback submitted under the Q-Submission Program for medical devices.

DATES: Submit either electronic or written comments on the collection of information by October 11, 2019.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before October 11, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of October 11, 2019. Comments received by mail/hand