

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-](https://www.fda.gov/advisory-committees/national-mammography-quality-assurance-advisory-committee/past-meeting-materials-national-mammography-quality-assurance-advisory-committee)

[meeting-materials-national-mammography-quality-assurance-advisory-committee](https://www.fda.gov/advisory-committees) 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.*

[FR Doc. 2019-17276 Filed 8-12-19; 8:45 am]

BILLING CODE 4164-01-P**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

delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2012-D-0530 for "Agency Information Collection Activities; Proposed Collection; Comment Request; Q-Submission Program for Medical Devices." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-8867, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44

U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Q-Submission Program for Medical Devices

OMB Control Number 0910-0756—Extension

The guidance entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program" (<https://www.fda.gov/media/114034/download>) provides an overview of the mechanisms available to submitters through which they can request feedback from or a meeting with FDA regarding certain potential or planned medical device submissions reviewed by the Center for Devices and Radiological Health (CDRH) and the Center for Biologics Evaluation and Research (CBER). The guidance provides recommendations regarding certain types of Q-Submissions, such as Pre-Submissions, Submission Issue Requests, Study Risk Determinations, Informational Meetings, and other Q-Submissions Types and other uses of the Q-Submission Program.

For clarity and consistency with the guidance that describes the program, we are requesting that the title of the information collection request, OMB control number 0910-0756, be changed to "Q-Submission Program for Medical Devices."

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

FDA center	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
CDRH	3,502	1	3,502	137	479,774
CBER	91	1	91	137	12,467
Total					492,241

¹ There are no capital costs or operating and maintenance cost associated with this of information.

Respondents are medical device manufacturers subject to FDA's laws and regulations. FDA's annual estimate of 3,593 submissions is based on experienced recent trends. FDA's administrative and technical staffs, who are familiar with Q-Submissions, estimate that an average of 137 hours is required to prepare a Q-Submission.

Our estimated burden for the information collection reflects an overall increase of 143,713 hours. We attribute this adjustment to an increase in the number of submissions we received based on FY18 data.

Dated: August 6, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-17345 Filed 8-12-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-N-2281]

Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the notice of public meeting entitled "Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Request for Comments" that appeared in the **Federal Register** of July 9, 2019. In the notice of public meeting, FDA requested comments on the use of complex adaptive and other novel investigation designs, data from foreign countries, real world evidence, and biomarkers and surrogate endpoints in animal drug development and regulatory decision making. The Agency is taking this action in response to a request for an

extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the notice of public meeting published July 9, 2019 (84 FR 32749). Submit either electronic or written comments by September 16, 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 September 16, 2019. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 16, 2019. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- **Federal eRulemaking Portal:** <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

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- **Mail/Hand Delivery/Courier (for written/paper submissions):** Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-N-2281 for "Incorporating Alternative Approaches in Clinical Investigations for New Animal Drugs; Public Meeting; Request for Comments." Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- **Confidential Submissions—**To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as