ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Registration Screens	299	1	0.15	44.85

Estimated Total Annual Burden Hours: 45.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–20121 Filed 8–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

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 6, 2017.

DATES: Authority for the National Mammography Quality Assurance Advisory Committee will expire on July 6, 2017 unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, Rm. 1643, Silver Spring, MD, 20993, *Sara.Anderson@fda.hhs.gov,* 301 796–7047.

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 statutory 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:

A. Developing appropriate quality standards and regulations for mammography facilities;

B. Developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;

C. Developing regulations with respect to sanctions;

D. Developing procedures for monitoring compliance with standards;

E. Establishing a mechanism to investigate consumer complaints;

F. Reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;

G. 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;

H. Determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and

I. 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 four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members shall include at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least 2 practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include 2 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 *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/NationalMammographyQualityAssuranceAdvisoryCommittee/ucm124611.htm* 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. 2). For general information related to FDA advisory committees, please visit us at *http://www.fda.gov/AdvisoryCommittees/default.htm.*

Dated: August 10, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–20050 Filed 8–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–D–0967]

Intent To Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices From Premarket Notification Requirements; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements,'' which updates an earlier guidance of the same title published in the **Federal Register** on July 1, 2015. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices from premarket notification requirements. Due to an administrative error, certain comments to this Docket were not considered prior to the July 1, 2015, guidance publication. These comments have now been considered. FDA believes additional devices and product codes are sufficiently well understood and do not require premarket notification to assure their safety and effectiveness. As such, FDA is updating and adding these to the guidance.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Intent to Exempt Certain Unclassified, Class II, and Class I Reserved Medical Devices from Premarket Notification Requirements'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Angela C. Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1666, Silver Spring, MD 20993–0002, 301–796–6380.

SUPPLEMENTARY INFORMATION:

I. Background

In the commitment letter (section 1.G of the Performance Goals and Procedures) that was drafted as part of the reauthorization process for the Medical Device User Fee Amendments of 2012, part of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144), FDA committed to identifying low-risk medical devices to exempt from premarket notification requirements. This guidance describes FDA's intent to exempt certain unclassified medical devices (that FDA intends to classify into class I or II), certain class II medical devices, and certain class I medical devices (that no longer meet the ''reserved'' criteria in section 510(*l*) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(*l*))) from premarket notification requirements. FDA believes the devices and product codes being added to this guidance document are sufficiently well understood and do not require 510(k) notification to assure their safety and effectiveness.

The draft of this guidance was made available in the **Federal Register** on August 1, 2014 (79 FR 44804). The comment period closed on September 30, 2014. FDA received 55 sets of comments on the draft guidance. FDA published a final guidance on July 1, 2015 (80 FR 37633). However, due to an administrative error, certain comments were not considered prior to the July 1, 2015, guidance publication. These comments have now been considered, and, based on that review, FDA is updating and adding certain devices and product codes to the guidance.

These comments requested that FDA include approximately 390 additional product codes in the guidance. Of these product codes, more than 110 were ones regulated by the Office of In Vitro Diagnostics and Radiological Health, which were outside of the scope of FDA's review to identify low-risk devices to ultimately exempt from premarket notification requirements. Additionally, for approximately 75 of the product codes, the comments noted that additional controls, such as conformance to recognized standards, would be necessary if 510(k)s were not submitted for these devices. Because the imposition of such controls would go beyond the scope of this guidance, FDA is not adding these device types and product codes to the guidance.

The comments also requested the addition of 18 product codes to the guidance that were either already in the final guidance published on July 1, 2015, exempt from premarket notification, or for which FDA is currently exercising enforcement discretion (Ref. 1). For example, more than 30 comments spoke to the inclusion of product code NUQ (Pad, Menstrual, Reusable), which was included in the draft guidance document, and remained in the final guidance document issued July 1, 2015.

FDA has considered the remaining product codes proposed in the comments and has determined that the following eight additional product codes should be included in the guidance document: Product code DTL, Adaptor, Stopcock, Manifold, Fitting, Cardiopulmonary Bypass (see 21 CFR 870.4290—Cardiopulmonary bypass adaptor, stopcock, manifold, or fitting); product code OCY, Endoscopic Guidewire, Gastroenterology-urology (see 21 CFR 876.1500—Endoscope and accessories); product code KOE, Dilator, urethral (see 21 CFR 876.5520—Urethral dilator); product code FTA, Light, Surgical, Accessories (see 21 CFR 878.4580—Surgical lamp); product code GZM, Analyzer, Rigidity (see 21 CFR 882.1020—Rigidity analyzer); product code GZO, Device, Galvanic Skin Response Measurement (see 21 CFR 882.1540—Galvanic skin response measurement device); product code HCJ, Device, Skin Potential Measurement (see 21 CFR 882.1560—Skin potential measurement device);