- Progress toward Meeting Legislatively Mandated Benchmark Requirements
- Update on Rigorous Evaluation Activities
- Home Visiting Program Continuous Quality Improvement (CQI) Efforts
- Administration of Home Visiting Program
- Technical Assistance Needs

The proposed data collection form is as follows:

ACF is requesting approval to renew and update the existing Tribal Home Visiting Guidance for Submitting an Annual or Final Report to the Secretary (OMB Control No. 0970–0409) that will include instructions for grantees to submit either an annual or final report on the progress of their program to the Secretary, depending on the reporting period.

Respondents: Tribal Maternal, Infant, and Early Childhood Home Visiting Program Managers (The information collection does not include direct interaction with individuals or families that receive the services).

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Total responses	Average burden hours per response	Total annual burden hours
Annual/Final Report to the Secretary (depending on reporting period)	25	1	1	50	1250

Estimated Total Annual Burden Hours: 1,250.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office Planning, Research and Evaluation, 370 L'Enfant Promenade SW, Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of theagency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2018–01705 Filed 1–29–18; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–0129]

Evaluating Inclusion and Exclusion Criteria in Clinical Trials; Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting entitled ''Evaluating Inclusion and Exclusion Criteria in Clinical Trials.'' Convened by the Duke-Robert J. Margolis, MD, Center for Health Policy at Duke University and supported by a cooperative agreement with FDA, the purpose of the public meeting is to bring the stakeholder community together to discuss a variety of topics related to eligibility criteria in clinical trials and their potential impact on patient access to investigational drugs, and how to facilitate the enrollment of a diverse patient population.

DATES: The public meeting will be held on April 16, 2018, from 8:30 a.m. to 5 p.m. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the National Press Club, 529 14th St. NW, Washington, DC 20045. For additional travel and hotel information, please refer to the following website: *https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials.* There will also be a live webcast for those unable to attend the meeting in person (see *Streaming Webcast of the Public Meeting*).

FOR FURTHER INFORMATION CONTACT: Dianne Paraoan, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 3326, Silver Spring, MD 20993, 301–796–2500, *Dianne.Paraoan@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting implements FDA's mandate under section 610 of the FDA Reauthorization Act of 2017 to convene a public meeting to discuss clinical trial inclusion and exclusion criteria that will ultimately inform an FDA guidance on this subject. Among other things, the public meeting will include discussion about various ways in which participation in clinical trials can be improved, including through alternative trial designs and expanded access trials (see Section II. Topics for Discussion at the Public Meeting).

Inclusion of relevant subpopulations in drug development programs helps ensure that approved products will be safe and effective for the population likely to be treated when the drug is marketed. However, certain eligibility criteria in clinical trials can exclude patient subgroups, resulting in the enrollment of study populations that may not be fully representative of that broader patient population. FDA has and will continue its efforts to encourage greater diversity in clinical trial populations. For example, FDA regulations require marketing applications to provide analyses of safety and effectiveness by demographic and other relevant subgroups (see 21 CFR 314.50(d)(5)(v)). In addition, in 2016, FDA published guidance on the collection of race and ethnicity data in clinical trials (available on FDA's guidance web page at *https://www.fda.gov/downloads/*

regulatoryinformation/guidances/ucm126396.pdf).

II. Topics for Discussion at the Public Meeting

Topics for discussion during this meeting include:

- The risks and benefits of participation in clinical trials as well as potential regulatory, geographical, and socioeconomic barriers to participation.
- the rationale for eligibility criteria in clinical trials, as well as the impact of exclusion criteria on the enrollment of populations, such as infants, children, pregnant and lactating women, elderly, individuals with advanced disease, and individuals with co-morbid conditions.
- alternative clinical trial designs that may increase enrollment of more diverse patient populations, while facilitating the collection of data to establish safety and effectiveness.
- how appropriate patient populations can benefit from the results of trials that employ alternative designs.
- how changes to eligibility criteria may impact the complexity and length of clinical trials, as well as the strength of data necessary to demonstrate safety and effectiveness.
- opportunities for using data from expanded access trials.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone. Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by April 12, 2018, midnight Eastern Time. There will be no onsite registration. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. Duke-Margolis will post on its website if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Sarah Supsiri at the Duke-Margolis Center for Health Policy, 202–791–9561, *sarah.supsiri@duke.edu,* no later than April 12, 2018.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast; archived video footage will be available at the Duke-Margolis website (*https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials*) following the meeting. Organizations are requested to register all participants, but to view using one connection per location whenever possible. Webcast participants will be sent technical system requirements in advance of the event. Prior to joining the streaming webcast of the public workshop, we recommend that you review these technical system requirements in advance.

Transcripts: Please be advised that transcripts will not be available.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Meeting Materials: All event materials will be provided to registered attendees via email prior to the workshop and publicly available at the Duke-Margolis website: *https://healthpolicy.duke.edu/events/evaluating-inclusion-and-exclusion-criteria-clinical-trials.*

Dated: January 24, 2018.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2018–01643 Filed 1–29–18; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–E–2082]

Determination of Regulatory Review Period for Purposes of Patent Extension; Cardiomems HF Monitoring System

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for CARDIOMEMS HF MONITORING SYSTEM and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by April 2, 2018. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by July 30, 2018. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

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 April 2, 2018. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of April 2, 2018. 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