Annual Responses: 861; *Total Annual Hours:* 12,930. (For policy questions regarding this collection contact Jaya Ghildiyal at (301) 492–5149.)

Dated: July 9, 2015.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2015–17285 Filed 7–10–15; 11:15 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Annual Report on Households Assisted by the Low Income Home Energy Assistance Program (LIHEAP)

OMB No.: 0970–0060.

Description: This statistical report is an annual activity required by statute (42 U.S.C. 8629) and Federal regulations (45 CFR 96.92) for the Low Income Home Energy Assistance Program (LIHEAP). Submission of the completed report is one requirement for LIHEAP grantees applying for Federal LIHEAP block grant funds. States, the District of Columbia, and the Commonwealth of Puerto Rico are required to report statistics for the previous Federal fiscal year on the number and income levels of LIHEAP applicants and assisted households, as well as the number of LIHEAP-assisted households with at least one member who is elderly, disabled, or a young child.

The statistical report requires States, the District of Columbia, and the Commonwealth of Puerto Rico to report on assisted households having at least one elderly person who is homebound; an unduplicated count of assisted households having at least one member who is elderly, disabled, or a young child; and an unduplicated count of assisted households receiving one or more types of LIHEAP assistance.

Insular areas receiving less than $200,000 annually in LIHEAP funds and Indian Tribal Grantees are required to submit data only on the number of households receiving heating, cooling, energy crisis, or weatherization benefits. The information is being collected for the Department's annual LIHEAP report to Congress. The data also provides information about the need for LIHEAP funds. Finally, the data are used in the calculation of LIHEAP performance measures under the Government Performance and Results Act of 1993. The additional data elements will improve the accuracy of measuring LIHEAP targeting performance and LIHEAP cost efficiency.

Respondents: State Governments, Tribal Governments, Insular Areas, the District of Columbia, and the Commonwealth of Puerto Rico.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Assisted household Report-Long Form	52	1	25	1,300
Assisted Household Report-Short Form	155	1	1	155
Applicant Household Report	52	1	13	676

Estimated Total Annual Burden Hours: 2,131.

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *infocollection@acf.hhs.gov.*

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. 2015–17166 Filed 7–13–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0597]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach To Monitoring

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 the collection of information concerning the development of comprehensive monitoring plans in the guidance.

DATES: Submit either electronic or written comments on the collection of information by September 14, 2015.

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

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455

Colesville Rd., COLE–14526, Silver Spring, MD 20993–0002, *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.

Guidance for Industry on Oversight of Clinical Investigations: A Risk-Based Approach To Monitoring

(OMB Control Number 0910–0733)—Extension

The guidance is intended to assist sponsors of clinical investigations in developing strategies for risk-based monitoring and plans for clinical investigations of human drug and biological products, medical devices, and combinations thereof. The guidance describes strategies for monitoring activities performed by sponsors, or by contract research organizations (CROs), that focus on the conduct, oversight, and reporting of findings of an investigation by clinical investigators. The guidance also recommends strategies that reflect a risk-based approach to monitoring that focuses on critical study parameters and relies on a combination of monitoring activities to oversee a study effectively. The guidance specifically encourages greater reliance on centralized monitoring methods where appropriate.

Under parts 312 and 812 (21 CFR parts 312 and 812), sponsors are required to provide appropriate oversight of their clinical investigations to ensure adequate protection of the rights, welfare, and safety of human subjects and to ensure the quality and integrity of the resulting data submitted to FDA. As part of this oversight, sponsors of clinical investigations are required to monitor the conduct and progress of their clinical investigations. The regulations do not specify how sponsors are to conduct monitoring of clinical investigations and, therefore, are compatible with a range of approaches to monitoring. FDA currently has OMB approval for the information collection required under part 812 (OMB control number 0910–0078) and part 312, including certain provisions under subpart D (OMB control number 0910–0014).

The collection of information associated with this guidance that approved under OMB control number 0910–0733 is as follows:

Development of Comprehensive Monitoring Plan: Section IV.D ''Monitoring Plan'' of the guidance recommends that sponsors develop a prospective, detailed monitoring plan that describes the monitoring methods, responsibilities, and requirements for each clinical trial. The plan should provide adequate information to those involved with monitoring to effectively carry out their duties. All sponsor personnel and CRO personnel who may be involved with monitoring (including those who review appropriate action, determine appropriate action, or both regarding potential issues identified through monitoring) should review the monitoring plan. The components of a monitoring plan are described in the guidance, including monitoring plan amendments (*i.e.,* the review and revision of monitoring plans and processes for timely updates).

FDA understands that sponsors currently develop monitoring plans; however, not all monitoring plans contain all the elements described in the guidance. Therefore, our burden estimate provides the additional time that a sponsor would expend in developing a comprehensive monitoring plan based on the recommendations in the guidance. FDA estimates that approximately 88 sponsors will develop approximately 132 comprehensive monitoring plans in accordance with the guidance and that the added burden for each plan will be approximately 4 hours to develop, including the time needed to prepare monitoring plan amendments when appropriate (a total of 528 hours).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Development of Comprehensive Monitoring Plan	88	1.5	132	4	528

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

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–17318 Filed 7–13–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2148]

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Draft 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 draft guidance entitled ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.'' This draft guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 13, 2015.

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 draft guidance document entitled ''Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices'' 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 draft 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: Jana Delfino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4236, Silver Spring, MD 20993–0002, 301–796–6503; or Sunder Rajan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1113, Silver Spring, MD 20993–0002, 301–796–4194.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide a detailed description of the information that should be included in a premarket notification for an MRDD. This document is an elaboration of the general requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with general information regarding the content and format of a 510(k) premarket notification. The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

This draft guidance is applicable to MRDDs as defined in 21 CFR 892.1000. An MRDD is intended for general diagnostic use to present images that reflect the spatial distribution and/or magnetic resonance spectra that reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). MRDDs are class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing.

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer, and software. This draft guidance document is applicable to premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, new components, and modifications to systems and components that have a significant impact on safety or effectiveness of the magnetic resonance diagnostic device. The information in this draft guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at *http://www.regulations.gov*. Persons unable to download an electronic copy of ''Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 340 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the