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. 2011–20646 Filed 8–12–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Application Requirements for the Low Income Home Energy Assistance Program (LIHEAP) Residential Energy Assistance Challenge Program (REACH) Model Plan.

OMB No.: 0970–0348.

Description: States, including the District of Columbia, Tribes, Tribal organizations and Territories applying for LIHEAP REACH funds must Submit an annual application prior to receiving Federal funds. The Human Services Amendments of 1994 (Pub. L. 103–252) amended the LIHEAP statute to add Section 2607B, which established the REACH program. REACH was funded for the first time in FY 1996 and is intended to: (1) Minimize health and safety risks that result from high energy burdens on low-income Americans; (2) reduce home energy vulnerability and prevent homelessness as a result of the inability to pay energy bills; (3) increase the efficiency of energy usage by low-income families, helping them achieve energy self-sufficiency; and (4) target energy assistance to individuals who are most in need. The REACH Model Plan clarifies the information being requested and ensures the submission of all the information required by statute. The form facilitates our response to numerous queries each year concerning the information that should be included in the REACH application. Submission of a REACH application and use of the REACH Model Plan is voluntary. Grantees have the option to use another format.

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
Reach model plan	51	1	72	3,672

Estimated Total Annual Burden Hours: 3,672.

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 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. *E-mail 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, *Fax:* 202–395–7285, *E-mail: OIRA_SUBMISSION@OMB.EOP.GOV, Attn:* Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2011–20613 Filed 8–12–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0577]

Draft Guidance for Industry and Food and Drug Administration Staff; Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review.'' The recommendations in this guidance are intended to provide greater clarity on FDA's decisionmaking process with regard to benefit-risk determinations in the premarket review of medical devices. 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 on this draft guidance before it begins work on the final version of the guidance, submit electronic or written comments on the draft guidance by November 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002; or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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: *For Devices Regulated by CDRH:* Rachel Turow, Center for Devices and

Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5449, Silver Spring, MD 20993–0002, 301–796–5094.

For Devices Regulated by CBER: Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852, 301–827–6210.

SUPPLEMENTARY INFORMATION:

I. Background

There are many factors that go into weighing the probable benefit of a device versus its probable risk. This draft guidance sets out the factors FDA considers when making this determination and explains them in detail. This draft guidance also gives examples of how the factors interrelate and how they may affect FDA's decisions. By clarifying FDA's decisionmaking process in this way, we hope to improve the predictability, consistency, and transparency of the review process for applicable devices.

This draft guidance also includes for public comment a draft worksheet that reviewers may use in making benefit-risk determinations. The worksheet is attached as appendix A to the guidance. This level of documentation is very helpful to maintaining the consistency of review across the different review divisions and better assuring that an appropriate decision is reached.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This draft guidance, when finalized, will represent the Agency's current thinking on factors to consider when making benefit-risk determinations in medical device premarket review. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm*. Guidance documents are also available at either *http://www.regulations.gov* or *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm*. To receive ''Factors to Consider When Making Benefit-Risk Determinations in Medical Device Premarket Review'' from CDRH, you may either send an e-mail request to *dsmica@fda.hhs.gov* to receive an electronic copy of the document or send a fax request to 301–847–8149 to receive a hard copy. Please use the document number 1772 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

FDA tentatively concludes that this draft guidance contains no new collections of information. This draft guidance refers to currently 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 814 have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: August 10, 2011.

Nancy K. Stade,

Deputy Director for Policy, Center for Devices and Radiological Health.

[FR Doc. 2011–20652 Filed 8–12–11; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0567]

Draft Guidance for Industry, Clinical Investigators, and Food and Drug Administration Staff; Design Considerations for Pivotal Clinical Investigations for Medical Devices; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Design Considerations for Pivotal Clinical Investigations for Medical Devices.'' This document is intended to provide guidance to those involved in designing clinical studies intended to support premarket submissions for medical devices and for FDA staff who review those submissions. This guidance document describes different study design principles relevant to the development of medical device clinical studies that can be used to fulfill premarket clinical data requirements. 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 on 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 November 14, 2011.

ADDRESSES: Submit written requests for single copies of the draft guidance document entitled ''Design Considerations for Pivotal Clinical Investigations for Medical Devices'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health (CDRH), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993–0002, or to the Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

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: Greg Campbell, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 2110, Silver Spring, MD 20993–0002, 301–796–5750.