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]

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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]

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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