Dated: August 1, 2011.

Daniel Holcomb,

Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. 2011–20033 Filed 8–5–11; 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: Refugee Assistance Program Estimates CMA—ORR–1.

OMB No.: 0970–0030.

Description: The ORR–1, Cash and Medical Assistance (CMA) Program Estimates, is the application for grants under the CMA program. The application is required by the Office of Refugee Resettlement (ORR) program regulations at 45 CFR 400.11(b). The regulation specifies that States must submit, as their application for this program, estimates of the projected costs they anticipate incurring in providing cash and medical assistance for eligible recipients and the costs of administering the program. Under the CMA program, States are reimbursed for the costs of providing these services and benefits for eight months after an eligible recipient arrives in this country. The eligible recipients for these services and benefits are refugees, Amerasians, Cuban and Haitian Entrants, asylees, Afghans and Iraqi with Special Immigrant Visas, and victims of a severe form of trafficking. States that provide services for unaccompanied refugee minors also provide an estimate for the cost of these services for the year for which they are applying for a grant.

Respondents:

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ORR–1	46	1	0.60	27.60

Estimated Total Annual Burden Hours: 27.60.

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. 2011–19973 Filed 8–5–11; 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: Low Income Home Energy Assistance Program (LIHEAP) Carryover and Reallotment Report.

OMB No.: 0970–0106.

Description: The LIHEAP statute and regulations require LIHEAP grantees to report certain information to HHS concerning funds forwarded and funds subject to reallotment. The 1994 reauthorization of the LIHEAP statute, the Human Service Amendments of 1994 (Pub. L. 103–252), requires that the Carryover and Reallotment Report for one fiscal year be submitted to HHS by the grantee before the allotment for the next fiscal year may be awarded.

The Administration for Children and Families is requesting no changes in the collection of data with the Carryover and Reallotment Report, a form for the collection of data, and the Simplified Instructions for Timely Obligations of LIHEAP Funds and Reporting Funds for Carryover and Reallotment. The form clarifies the information being requested and ensures the submission of all the required information. The form facilitates our response to numerous queries each year concerning the amounts of obligated funds. Use of the form 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
Carryover and Reallotment Report	192	1	3	576

Estimated Total Annual Burden Hours: 576.

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. 2011–19974 Filed 8–5–11; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0085]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Cooperative Manufacturing Arrangements for Licensed Biologics

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 7, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *Fax:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910–0629. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry: Cooperative Manufacturing Arrangements For Licensed Biologics—(OMB Control Number 0910–0629)—Extension

The guidance document provides information concerning cooperative manufacturing arrangements applicable to biological products subject to licensure under section 351 of the Public Health Service Act (42 U.S.C. 262). The guidance addresses several types of manufacturing arrangements (*i.e.,* short supply arrangements, divided manufacturing arrangements, shared manufacturing arrangements, and contract manufacturing arrangements) and describes certain reporting and recordkeeping responsibilities, associated with these arrangements, including the following: (1) Notification of all important proposed changes to production and facilities; (2) notification of results of tests and investigations regarding or possibly impacting the product; (3) notification of products manufactured in a contract facility; and (4) standard operating procedures.

(1) Notification of All Important Proposed Changes to Production and Facilities

Each licensed manufacturer in a divided manufacturing arrangement or shared manufacturing arrangement must notify the appropriate FDA center regarding proposed changes in the manufacture, testing, or specifications of its product, in accordance with § 601.12 (21 CFR 601.12). In the guidance, we recommend that each licensed manufacturer that proposes such a change should also inform other participating licensed manufacturer(s) of the proposed change.

For contract manufacturing arrangements, we recommend that the contract manufacturer should share with the license manufacturer all important proposed changes to production and facilities (including introduction of new products or at inspection). The license holder is responsible for reporting these changes to FDA (§ 601.12).

(2) Notification of Results of Tests and Investigations Regarding or Possibly Impacting the Product

In the guidance, we recommend the following for contract manufacturing arrangements:

- The contract manufacturer should fully inform the license manufacturer of the results of all tests and investigations regarding or possibly having an impact on the product; and
- The license manufacturer should obtain assurance from the contractor that any FDA list of inspectional observations will be shared with the license manufacturer to allow evaluation of its impact on the purity, potency, and safety of the license manufacturer's product.

(3) Notification of Products Manufactured in a Contract Facility

In the guidance, we recommend for contract manufacturing arrangements that a license manufacturer cross reference a contract manufacturing facility's Master Files only in circumstances involving certain proprietary information of the contract manufacturer, such as a list of all products manufactured in a contract facility. In this situation, the license manufacturer should be kept informed of the types or categories of all products manufactured in the contract facility.

(4) Standard Operating Procedures

In the guidance, we remind the license manufacturer that the license manufacturer assumes responsibility for compliance with the applicable product and establishment standards (21 CFR 600.3(t)). Therefore, if the license manufacturer enters into an agreement with a contract manufacturing facility, the license manufacturer must ensure that the facility complies with the applicable standards. An agreement between a license manufacturer and a contract manufacturing facility normally includes procedures to regularly assess the contract manufacturing facility's compliance. These procedures may include, but are not limited to, review of records and manufacturing deviations and defects, and periodic audits.

For shared manufacturing arrangements, each manufacturer must submit a separate biologics license application (BLA) describing the manufacturing facilities and operations applicable to the preparation of that manufacturer's biological substance or product (§ 601.2(a)). In the guidance, we state that we expect the manufacturer that prepares (or is responsible for the preparation of) the product in final form for commercial distribution to assume primary responsibility for providing data demonstrating the safety, purity, and potency of the final product. We also state that we expect the licensed finished product manufacturer to be primarily responsible for any post-approval obligations, such as