ANNUAL BURDEN ESTIMATES

Instruments	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
§ 1305.4(l) Eligibility determination records *(sample form)*	1,600	478	.10	76,480
§ 1305.4(d)(2)	20	1	2	40
§ 1305.4(h),(i), and (j)	1,600	1	15	24,000
§ 1305.4(l) Other Record Keeping	1,600	1	15	24,000
Estimated Total Annual Burden Hours				124,520

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, Fax: 202–395–7285, Email: *OIRA_SUBMISSION@OMB.EOP.GOV*.

Attn: Desk Officer for the Administration for Children and Families.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–32565 Filed 12–24–15; 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: Refugee Microenterprise and Refugee Home-Based Child Care Microenterprise Development.

OMB No.: 0970.

Description: New data collection tool for refugee microenterprise and Refugee Home-Based Child Care Microenterprise Program.

Respondents: Refugee Microenterprise Development Grantees and Refugee Home-Based Child Care Microenterprise Development.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Refugee Microenterprise Development	22	8	4	88
Refugee Home-Based Child Care Microenterprise Development	23	7	4	92
Total Burden				180

Estimated Total Annual Burden Hours: (180 hours × $30 per hour) $4,500 per year.

Explanation

The Refugee Microenterprise Development Program

- Currently, there are twenty two grantees (respondents) in the program and the semi-annual progress, which includes the data and information required, is submitted twice per year.
- The request covers one form (Form I. attached) which includes eight data points. Based on experience (the information was provided by technical assistance service provider in the past), it takes about two hours per respondent per six months (*i.e.,* four hours per year per grantee (respondent) or 88 hours per year for all respondents) to complete the form.
- No survey will be undertaken since the collection of this data (information) is part of the implementation process of the project and its collection and reporting does not constitute a separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have Down Home database which captures and stores the data required for reporting. The grantee uploads the semi-annual report in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

The Refugee Home-Based Child Care Microenterprise Development Group

- Currently, there are twenty three grantees (respondents) in the program and the semi-annual progress.
- The request covers one form (Form II. attached) which includes seven data points. It takes about two hours per respondent per six months (*i.e.,* four hours per year grantee (respondent) or 92 hours per year for all respondents) to complete the form.
- The collection of this data (information) is part of the process and its collection and reporting does not include separate and additional cost to the grantees (respondents). The cost is covered by the grant the grantee receives. The grantees have database which captures and stores the data required for reporting. The grantee uploads the data required in Grant Solution where it is stored. ORR derives the data it requires for reporting and management decision from Grant Solution.

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. 2015–32580 Filed 12–24–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2013–E–1692 and FDA–2013–E–1691]

Determination of Regulatory Review Period for Purposes of Patent Extension; KADCYLA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) has determined the regulatory review period for KADCYLA 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 human biological product.

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 February 26, 2016. 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 June 27, 2016. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://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 *http://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):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket Nos. FDA–2013–E–1692 and FDA–2013–E–1691 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; KADCYLA''.

Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions'', publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential''. Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years