

Review Final Determination will be posted as part of the rate review consumer disclosure information on an HHS Web site.

Final Justification for an Unreasonable Rate Increase

The proposed rule states that if a health insurance issuer implements a rate increase determined by HHS or a State to be unreasonable, the health insurance issuer must provide a Final Justification for an Unreasonable Rate Increase. In the Final Justification, issuers would have to provide a short statement about why they are electing to implement an unreasonable rate increase. This statement would be entered into a data entry text box in the Rate Review Data Collection System and would not need to be more than a paragraph or two in length. There is no form or instructions associated with this statement apart from the requirements provided in the proposed regulation.

The Final Justification Statement will be posted on an HHS Web site in the same location as the Preliminary Justification and Rate Review Final Determination. Additionally, health insurance issuers implementing rate increases that were determined to be unreasonable, must post all of this information—the Preliminary Justification, the Rate Review Final Determination, and the Final Justification Statement on their Web sites for a period of 3 years.

Form Number: CMS-10379; (OMB Control No. 0938-NEW) *Frequency:* Annually; *Affected Public:* Private Sector; *Number of Respondents:* 1,543 *Number of Responses:* 1,546; *Total Annual Hours:* 8,418. (For policy questions regarding this collection, contact Sally McCarty at (301) 492-4489 or RateReview@hhs.gov. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS' Web site at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or e-

mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office at 410-786-1326.

In commenting on the proposed information collections please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be submitted in one of the following ways by *May 2, 2011*:

1. Electronically. You may submit your comments electronically to <http://www.regulations.gov>. Follow the instructions for "Comment or Submission" or "More Search Options" to find the information collection document(s) accepting comments.

2. By regular mail. You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4-26-05, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

Dated: February 23, 2011.

Martique Jones,

Director, Regulations Development Group, Division B, Office of Strategic Operations and Regulatory Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Child Care and Development Fund Tribal Plan Preprint—ACF-118-A.

OMB No.: 0970-0198.

Description: The Child Care and Development Fund (CCDF) Plan (the Plan) for Tribes (Indian Tribes, Tribal consortia and Tribal organizations) is

required from each CCDF Lead agency in accordance with Section 658E of the Child Care and Development Block Grant Act of 1990, as amended (Pub. L. 101-508, Pub. L. 104-193, and 42 U.S.C. 9858). The implementing regulations for the statutorily required Plan are set forth at 45 CFR 98.10 through 98.18. The Plan, submitted on the ACF 118-A, is required biennially, and remains in effect for two years. The Plan provides ACF and the public with a description of, and assurance about, the Tribal child care program. The ACF 118-A is currently approved through September 30, 2011, making it available to Tribes needing to submit Plan Amendments through the end of the FY 2011 Plan Period. However, on July 1, 2011, Tribes will be required to submit their FY 2012-2013 Plans for approval by September 30, 2011. Consistent with the statute and regulations, ACF requests revision of the ACF 118-A with minor corrections and modifications.

The Office of Child Care(OCC) has given thoughtful consideration to the comments received from the 1st Public Notice. OCC has revised the document to reflect some of the changes made to minimize the burden of the collection of information on respondents. The revised document contains revisions to improve the accuracy and clarity of questions in order to improve the quality of information that is collected. This second Public Comment Period provides an opportunity for the public to submit comments to the Office of Management and Budget (OMB).

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.

Respondents:

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	257	0.5	120	15,420

Estimated Total Annual Burden Hours: 15,420.

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. 2011-4418 Filed 2-28-11; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0099]

Agency Information Collection Activities; Proposed Collection; Comment Request; Followup Study for Infant Feeding Practices Study II

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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a study entitled "Followup Study for Infant Feeding Practices Study II."

DATES: Submit either electronic or written comments on the collection of information by May 2, 2011.

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:
Denver Presley, Office of Information

Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, 301-796-3793.

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 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.

Followup Study for Infant Feeding Practices Study II (OMB Control Number 0910-NEW)

I. Background

FDA is planning to conduct a survey of the mothers who participated in the Infant Feeding Practices Study II (IFPS II) (Ref. 1). The IFPS II sample was drawn from a commercial consumer opinion panel, and so participants are expected to be easier to re-contact than would be the case for a random sample of the population. Some participants will still be panel members. The purpose of the study is to enhance FDA's understanding of the associations between infant feeding practices and diet quality, food allergy, overweight and obesity, and other health and development outcomes in young children.

The study results will be used to help the Agency to understand the possible role of infant feeding practices in the development and progression of food allergy and childhood overweight and obesity, in addition to resistance to infection and other health and development outcomes. The results of the study will not be used to develop population estimates.

The data will be collected by a mailed questionnaire from most respondents and by telephone from those who do not respond to the mailed questionnaire. The study will focus on the following types of information: The child's consumption of various food groups; the child's other consumption practices (such as how often the child eats dinner with a parent and how often the child eats from fast food restaurants); the mother's control over the child's eating patterns; the child's physical activity and time spent watching a screen (TV or computer); the child's sleep patterns; extent of the child's cognitive stimulation at home; the child's height, weight, and waist circumference; the child's visits to a dentist and number of cavities; number of the child's recent physician visits; number of various types of infections the child had in the past year; whether the child has various health conditions including digestive problems, eczema, food allergy, respiratory allergy, attention deficit disorder, developmental delay, anxiety problems, depression, or asthma; the child's social development; the child's family medical history; the mother's height and weight, physical activity, depression, pregnancies subsequent to the sample child and whether subsequent children were breastfed, and employment conditions; the mother or child's participation in certain government programs; and the child's potential exposure to certain environmental contaminants including cigarette smoke and pesticides. A demographic questionnaire will also be mailed to respondents for whom current information is not available through the consumer opinion panel. Participation in the study is voluntary.

To refine the questionnaire used in the study, a pretest will be conducted with 100 participants, 91 by mailed questionnaire and 9 by telephone interview. We estimate that it will take a respondent 20 minutes (0.33 hours) to complete the survey and 5 minutes (0.08 hours) to complete debriefing questions for the pretest, for a total of 25 minutes (0.42 hours) per respondent and a total of 38 hours for the mailed and 4 hours for the interview pretest. The sample for the pretest will be panel members who are mothers of children 5 to 7 years old