Attachment C

Federal Register Notice Announcing the 60-day Public Comment Period

financial resources necessary to comply with a collection of information are excluded from the burden estimate if the reporting, recordkeeping, or disclosure activities needed to comply are usual and customary because they would occur in the normal course of activities.

In this request for extension of OMB approval under the PRA, FDA is combining the burden hours associated with OMB control numbers 0910–0395 (collection entitled ''Food Labeling: Nutrition Labeling of Dietary Supplements on a 'Per Day' Basis'') and 0910–0515 (collection entitled ''Food Labeling: Trans Fatty Acids in Nutrition Labeling'') with the burden hours approved under OMB control number 0910–0381 (collection entitled ''Food Labeling Regulations'').

Dated: July 8, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–16869 Filed 7–14–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Agency Recordkeeping/Reporting Requirements Under Emergency Review by the Office of Management and Budget (OMB)

Title: Child Care and Development Fund (CCDF) Financial Report, Form ACF–696T (Tribes)

OMB No.: 0970–0195.

Description: Tribes use the Financial Report Form ACF–696T to report Child Care and Development Fund (CCDF) expenditures. Authority to collect and report this information is found in Section 6580 of the Child Care and Development Block Grant Act of 1990, as revised. In addition to the Program Reporting Requirements set forth in 45 CFR Part 98, Subpart H, the regulations at 45 CFR 98.65(g) and 98.67(c)(1) authorize the Secretary to require financial reports as necessary.

Tribal grantees submit the ACF–696T report on an annual basis on behalf of the Tribal Lead Agency administering the Child Care and Development Fund (CCDF).

The American Recovery and Reinvestment Act (ARRA) of 2009, (Pub. L. 111–5) provides an additional $2 billion for the Child Care and Development Fund to help States, Territories, and Tribes provide child care assistance to low income working families. CCDF Program Instruction (CCDF–ACF–PI–2009–03) provided guidance on ARRA spending requirements.

Section 1512 of the ARRA legislation requires recipients to report quarterly spending and performance data on the public Web site, ''Recovery.gov''. Federal agencies are required to collect ARRA expenditure data and performance data and these data must be clearly distinguishable from the regular CCDF (non-ARRA) funds. To ensure transparency and accountability, the ARRA requires Federal agencies and grantees to track and report separately on expenditures from funds made available by the stimulus bill. Office of Management and Budget (OMB) guidance implementing the ARRA legislation indicates that agencies requiring additional information for oversight should rely on existing authorities and reflect these requirements in their award terms and conditions as necessary, following existing procedures. Therefore, to capture ARRA expenditures, the ACF 696T has been modified (by the addition of two columns) for reporting ARRA data. In addition, a new data element will ask Tribes to estimate the number of child service months funded with ARRA dollars. The collection will not duplicate other information.

Respondents: Tribal CCDF Agencies.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
CCDF Tribal Plan	232	1	8	1,856

Estimated Total Annual Burden Hours: 1,856.

Additional Information:

ACF is requesting that OMB grant a 90-day approval for this information collection under procedures for emergency processing by July 15, 2009. A copy of this information collection, with applicable supporting documentation, may be obtained by calling the Administration for Children and Families, Reports Clearance Officer, Robert Sargis at (202) 690–7275.

Comments and questions about the information collection described above should be directed to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for ACF, Office of Management and Budget, Paperwork Reduction Project, 725 Street, NW., Washington, DC. 20503, FAX (202) 395–6974.

Dated: June 6, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–16478 Filed 7–14–09; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60Day–09–09CC]

Proposed Data Collections Submitted for Public Comment and Recommendations

In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) is soliciting public comment on the specific aspects of the proposed information collection described below. To request more information on the proposed projects or to obtain a copy of the data collection

plans and instruments, call 404–639–5960 and send comments to Maryam I. Daneshvar, CDC Acting Reports Clearance Officer, 1600 Clifton Road, MS–D74, Atlanta, GA 30333; or send an e-mail to *omb@cdc.gov.*

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Written comments should be received within 60 days of this notice.

Proposed Project

CDC American Recovery and Reinvestment Act of 2009 (ARRA) Performance Progress Report—New—Office of the Chief Operating Officer (OCOO), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The American Recovery and Reinvestment Act of 2009 was signed into law on February 17, 2009, Public Law 111–5 (''Recovery Act''). The purpose of this proposed data collection is to collect quarterly performance information for all CDC grants and cooperative agreements funded under the Recovery Act. This will allow CDC to receive reports on recipient performance measures as set forth in the applicable Funding Opportunity Announcement (FOA) and Notice of Grant Award. This requirement is in addition to the reporting requirements of Section 1512 of the Recovery Act, set forth by the Office of Management and Budget (OMB) under the data collection instrument titled ''Standard Data Elements for Reports under Section 1512 of the American Recovery and Reinvestment Act of 2009, Public Law 111–5 (Grants, Cooperative Agreements and Loans).''

The form CDC proposes to use is a modified Performance Progress Report (SF–PPR) which was successfully piloted by the Administration for Children and Families (ACF). CDC intends to use this modified form for quarterly standard reporting of performance measures set forth in the applicable FOA and Notice of Grant Award for all CDC Recovery Act funded grants and cooperative agreements. In addition to allowing for uniformity of information collection, this format will support systematic electronic collection and submission of information. The form contains identifying data elements and a section for a performance narrative.

There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden (in hours)
Recipients using CDC ARRA Performance Progress Report	405	4	1.5	2430

Dated: July 8, 2009.

Maryam I. Daneshvar,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

[FR Doc. E9–16772 Filed 7–14–09; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0283]

Draft Guidance for Industry on Postmarketing Studies and Clinical Trials; Implementation of the Federal Food, Drug, and Cosmetic Act; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Postmarketing Studies and Clinical Trials—Implementation of Section 505(o) of the Federal Food, Drug, and Cosmetic Act.'' The Food and Drug Administration Amendments Act of 2007 (FDAAA) added new provisions to the Federal Food, Drug, and Cosmetic Act (the act) authorizing FDA to require certain postmarketing studies and clinical trials for prescription drugs and biological products approved under the act or the Public Health Service Act (the PHS Act). This draft guidance provides information on the implementation of the new provisions and a description of the types of postmarketing studies and clinical trials that will generally be required under the new legislation (postmarketing requirements (PMRs)) and the types that will generally be agreed-upon commitments (postmarketing commitments (PMCs)) because they do not meet the new statutory criteria for required postmarketing studies and clinical trials.

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 written or electronic comments on the draft guidance by October 13, 2009.

ADDRESSES: Submit written requests for single copies of this draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002; or 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. The draft guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 301–827–1800. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Nancy Clark, Center for Drug Evaluation and Research, Food and Drug