ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Telephone Interview	120	1	0.75	90	90
Key Leaders Interview	24	1	1.5	36	36
Other Leaders Interview	30	1	1	30	30
Front-line Staff Interview	96	1	1	96	96
Governing Body/Policy Council Interview	72	1	1	72	72
Local Education Agency Interview	12	1	1	12	12
Parent Focus Group	144	1	1.5	216	216

Estimated Total Annual Burden Hours: 552.

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2013–00593 Filed 1–15–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Mother and Infant Home Visiting Program Evaluation: Follow-up data collection on family outcomes.

OMB No.: 0970–0402.

Description: In 2011, the Administration for Children and Families (ACF) and Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS) launched a national evaluation called the Mother and Infant Home Visiting Program Evaluation (MIHOPE). This evaluation, mandated by the Affordable Care Act, will inform the federal government about the effectiveness of the Maternal, Infant, and Early Childhood Home Visiting (MIECHV) program in its first few years of operation, and provide information to help states develop and strengthen home visiting programs in the future. MIHOPE has two phases. Phase 1 includes baseline data collection and implementation data; Phase 2 includes follow up data collection. OMB approved a data collection package for Phase 1 in July 2012. The purpose of the current document is to request approval of data collection efforts for Phase 2.

Data collected during Phase 2 will include the following: (1) A one-hour family follow-up survey, (2) 30-minutes of observed interactions between the parent and child, (3) a direct assessment of child development, (4) measurement of mother's weight and child's height and weight, (5) collection of saliva from the mother and child for purposes measuring cotinine, an indicator of smoking behavior and exposure to second-hand smoke, and cortisol, an indicator stress exposure and regulation, and (6) extend collection of weekly home visitor logs on home visiting services until a family is no longer receiving services.

Data collected during Phase 2 will be used to estimate the effects of MIECHV-funded programs on seven domains specified for the evaluation in the ACA: (1) Prenatal, maternal, and newborn health; (2) child health and development, including maltreatment, injuries, and development; (3) parenting; (4) school readiness and academic achievement; (5) crime or domestic violence; (6) family economic self-sufficiency; and (7) use of other community resources. Data collected during Phase 2 will also be used to assess the differences in services used between families who receive home visiting and a comparison group, and to assess the quantity of home visiting services received by families.

Respondents: The respondents in Phase 2 will include 4335 parents who are enrolled in the study. Data collection activities will take place over a three-year period.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Home visitor logs	170	50	0.09	765
Family follow-up survey	1445	1	1.0	1445
Direct parent-child interactions	2890	1	0.5	1445
Direct child assessments	1445	1	0.7	1012

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Collecting saliva to measure cotinine and cortisol, and measuring height and weight	2890	1	0.3	867

Estimated Total Annual Burden Hours: 5,334

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: OPRE Reports Clearance Officer. All requests should be identified by the title of the information collection. Email address: *OPREinfocollection@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.

Steven M. Hanmer,

Reports Clearance, Officer.

[FR Doc. 2013–00592 Filed 1–15–13; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0921]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal

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 (the PRA).

DATES: Fax written comments on the collection of information by February 15, 2013.

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 emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0645. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400T, Rockville, MD 20850, *domini.bean@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.

Electronic Submission of Food and Drug Administration Adverse Event Reports and Other Safety Information Using the Electronic Submission Gateway and the Safety Reporting Portal—21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 1271.350 and Part 803 (OMB Control Number 0910–0645)—Revision

The FDA Safety Reporting Portal (the SRP) (formerly referred to as the MedWatch^{Plus} Portal and Rational Questionnaire) and the Electronic Submission Gateway (ESG) are the Agency's electronic systems for collecting, submitting, and processing adverse event reports and other safety information for FDA-regulated products. To ensure the safety and identify any risks, harms, or other dangers to health for all FDA-regulated human and animal products, the Agency needs to be informed whenever an adverse event, product quality problem, or product use error occurs. This risk identification process is the first necessary step that allows the Agency to gather the information necessary to be able to evaluate the risk associated with the product and take whatever action is necessary to mitigate or eliminate the public's exposure to the risk.

Some adverse event reports are required to be submitted to FDA (mandatory reporting) and some adverse event reports are submitted voluntarily (voluntary reporting). Requirements regarding mandatory reporting of adverse events or product problems have been codified in 21 CFR parts 310, 314, 514, 600, 803 and 1271, specifically §§ 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a) (21 CFR 310.305, 314.80, 314.98, 314.540, 514.80, 600.80, 803.30, 803.40, 803.50, 803.53, 803.56 and 1271.350(a)). Many of the adverse event reports submitted to FDA are currently filed in paper format using FDA Forms FDA 3500, 3500A, 1932, and 1932a, approved under OMB control numbers 0910–0284 and 0910–0291. This notice solicits comments on adverse event reports filed electronically via the SRP and the ESG, approved under OMB control number 0910–0645.

I. The FDA Safety Reporting Portal Rational Questionnaires

FDA currently has OMB approval to receive three types of adverse event reports electronically via the SRP using rational questionnaires. FDA sought comments on the extension of OMB approval for the existing three rational questionnaires, as well as comments on a proposed fourth rational questionnaire that will be used for a new safety reporting program being launched by the Center for Tobacco Products (CTP).

A. Reportable Food Registry Reports

The Food and Drug Administration Amendments Act of 2007 (Pub. L. 110–85) (FDAAA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by creating a new section 417 (21 U.S.C. 350f), Reportable Food Registry (RFR or the Registry). Section 417 of the FD&C Act defines ''reportable food'' as an ''article of food (other than infant formula or dietary supplements) for which there is a reasonable