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Dated: December 12, 2012.

John Howard,

Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention.

[FR Doc. 2012–30515 Filed 12–18–12; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Comment Request

Title: Mother and Infant Home Visiting Program Evaluation—Strong Start: Data collection.

Description: In September 2012, the Administration for Children and Families (ACF), the Centers for Medicare and Medicaid Services (CMS), and the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services (HHS) launched an evaluation called the Mother and Infant Home Visiting Program Evaluation—Strong Start (MIHOPE—Strong Start). The study will evaluate the effectiveness of two evidence-based home visiting models—Healthy Families America and Nurse Family Partnership—at improving birth outcomes for women who are enrolled in Medicaid. The evaluation is part of the Strong Start for Mothers and Newborns initiative, which is informing the federal government about the effects of prenatal interventions that may provide better care, improved health, and reduced medical costs by improving birth outcomes.

Data collected for MIHOPE-Strong Start will include the following: (1) A 20-minute baseline family survey, (2) two-hour semi-structured interviews with state administrators of the Maternal, Infant, and Early Childhood Home Visiting program, (3) web-based surveys with program managers of local home visiting programs, and (4) web-based surveys with home visitors in those programs. In addition, the study

will collect information on dosage and referrals from home visiting programs' management information systems, and will collect information on family outcomes from state and vital records systems.

These data will be combined with administrative data to estimate the effects of the home visiting programs on birth outcomes and infant health and health care in the first year, both overall and for groups of families and programs. Data on program implementation will provide information on how local programs operate and the dosage of home visiting services that families receive.

Respondents: The respondents will include 20,000 women who are no more than seven months pregnant when they enter the study, 8 state administrators, 68 program managers, and 782 home visitors. Data collection activities will take place over a three-year period. The annual burden on the public for these activities is estimated to be 2,435 hours over a three year period (approximately 21 minutes per person over three years).

Copies of the proposed instruments and brief project description 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.

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.

A comment is best assured of having its full effect if it is received within 30 days of this publication. Written comments and recommendations for the proposed information collection should be sent directly to Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington,

DC 20447, Attn: OPRE Reports Clearance Officer.

Steven M. Hanmer,

Reports Clearance Officer.

[FR Doc. 2012–30367 Filed 12–18–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0976]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance: Emergency Use Authorization of Medical Products

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 January 18, 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 0910–0595. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@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.

Reporting and Recordkeeping for Emergency Use Authorization of Medical Products (OMB Control Number 0910–0595)—Extension

The guidance describes the Agency's general recommendations and procedures for issuance of emergency