inclusion (i.e., nursing homes). A contractor will conduct face-to-face interviews with the chairs of the Violence Prevention Committees at 20 nursing homes, who as stated in regulations, are in charge of overseeing compliance efforts. These individuals will include nursing home administrators. The purpose of the interviews is to measure compliance to the state regulations (Aim 1). The interview form was pilot-tested by the study team in the Fall 2010 and includes the following components as mandated in the regulations: violence prevention policies, reporting systems for violent events, violence prevention committee, written violence prevention plan, violence risk assessments, post incident response and violence prevention training. The nursing home's policy and procedures documents will be obtained by the contractor to provide details about their workplace violence prevention program. Questions will also be asked about barriers and facilitators to developing the violence prevention program. These data will be collected in the post-regulation time period.

A contractor will also collect assault injury data from nursing home violent event reports 3 years pre-regulation (2009–2011) and 3 years post-regulation (2012–2014). This data will be collected from existing OSHA logs. The purpose of collecting these data is to evaluate changes in assault injury rates before and after enactment of the regulations (Aim 3). The following information will be abstracted from the OSHA logs: date, time and location of the incident; identity, job title and job task of the victim; identity of the perpetrator; description of the violent act, including whether a weapon was used; description of physical injuries; number of employees in the vicinity when the incident occurred, and their actions in response to the incident; recommendations of police advisors, employees or consultants, and; actions taken by the facility in response to the incident. No employee or perpetrator identifiable information will be collected.

In addition to nursing homes, home healthcare aides will also be recruited. These home healthcare aides will be recruited from a mailing list of home healthcare aides certified from the State of New Jersey Division of Consumer Affairs Board of Nursing. The mailing list was selected as the population source of workers due to the ability to capture all home healthcare aides in New Jersey. Therefore, a sampling frame based on home healthcare aides will be used to select workers to participate in the study. A random sample of 4000 (1333 annually) home healthcare aides will be recruited for study participation. A third-party contractor will be responsible for sending the survey to the random sample of 4000 home healthcare aides (1333 annually). The Health Professionals and Allied Employees union will promote the survey to their members. To maintain the worker's anonymity, the home healthcare agency in which he/she works will not be identified. The survey will describe the workplace violence prevention training home healthcare aides receive following enactment of the New Jersey regulations (Aim 2). There are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Respondents	Form	No. of respondents	No. of responses per respondent	Average burden per response (in hrs)	Total burden (in hrs)
Hospital Administrator	Interview	17	1	1	17
Nursing Administrator	Interview	7	1	1	7
Nurse Survey	Survey	1333	1	20/60	445
Home Healthcare Aides	Survey	1333	1	20/60	445
Total					914

Kimberly S. Lane,

Deputy Director, Office of Science Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

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BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; 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 interview with the parent, (2) 30-minutes of observed interactions between the parent and child, (3) a direct assessment of child development, and (4) collection of saliva from the parent or child for purposes of measuring cotinine, an indicator of smoking behavior and exposure to second-hand smoke, and other health and stress indicators. Saliva analysis would not include assessment for illegal drug use or DNA.

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) coordination of referrals for and provision 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.

Respondents: Respondents in Phase 2 will include parents and children 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
Survey of parents in the study	1360	1	1.0	1360
Observed parent-child interactions	2720	1	0.5	1360
Direct assessments of children	2720	1	0.7	1904
Collecting saliva to measure cotinine	2720	1	0.1	272
Estimated Total Annual Burden Hours				4896

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. 2012–18702 Filed 7–31–12; 8:45 am]

BILLING CODE 4184–22–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0813]

Agency Information Collection Activities; Proposed Collection; Comment Request; Applications for Food and Drug Administration Approval To Market a New Drug; Revision of Postmarketing Reporting Requirements—Discontinuance

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 including each proposed extension of an existing collection of information and to allow 60 days for public comment in response to the notice. This notice solicits comments on the reporting requirements contained in FDA's regulations on postmarketing reporting of information pertaining to drug shortages.

DATES: Submit either electronic or written comments on the collection of information by October 1, 2012.

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: Juanmanuel Vilela, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7651, *juanmanuel.vilela@fda.hhs.gov.*

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 [,including each proposed [extension/reinstatement] of an existing 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,