

the nomination form with a reviewer or abstractor in person or by phone, and to describe to the reviewer how information was obtained from electronic records, chart reviews, or other sources. Finalists may be eliminated based on the results of data verification.

Each remaining finalist, or Champion, will be asked to participate in a semi-structured interview. The interview will provide detailed information about the strategies employed by the practice or health system to achieve exemplary rates of hypertension control, including barriers and facilitators for those strategies. The interview will focus on systems and processes and should take no preparation time by the finalist. The estimated burden to the respondent is two hours, which includes time to review the interview protocol with the interviewer, respond to the interview questions, and review qualitative data.

OMB approval is requested for three years. On an annual basis, CDC estimates that information will be collected from 1,750 nominees using the nomination form, at most 30 data verification forms, and at most 30 semi-structured interviews that include review of qualitative data. The number of Champions recognized in the first year of the challenge may be less than 30. As the Challenge becomes known, the number of recognized Champions may increase to a maximum of 30.

The overall goal of the Million Hearts™ initiative is to improve the quality of care delivered to hypertensive patients. CDC will use the information collected through the Million Hearts™ Hypertension Control Challenge to increase widespread attention to hypertension at the clinical practice level, improve understanding of successful implementation strategies at the health system level, bring prestige to

organizations that invest in hypertension control, and motivate individual practices to strengthen their hypertension control efforts. Although some providers and healthcare systems routinely provide data on hypertension control rates to entities such as quality improvement committees, these entities do not collect or disseminate information about the clinic processes used to achieve hypertension control. Information collected through the Million Hearts™ Hypertension Control Challenge will link success in clinical outcomes of hypertension control with information about procedures that can be used to achieve similar favorable outcomes. The Challenge will allow interested providers and health care systems to replicate successful the strategies.

Participation is voluntary and there are no costs to respondents other than their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondent	Form name	Number of respondents	Number of responses per respondent	Avg. burden per response (in hr)	Total burden (in hr)
Physicians (Single or Group Practices)	Million Hearts™ Hypertension Control Champion Nomination form.	1,750	1	.5	875
Finalists	Data Verification Form	30	1	1	30
Selected Champion	Semi-structured Interview	30	1	2	60
Total					965

Dated: December 13, 2012.

Ron A. Otten,

Director, Office of Scientific Integrity (OSI), Office of the Associate Director for Science (OADS), Office of the Director, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket Number CDC-2012-0014; NIOSH-260]

Silver Nanoparticles (AgNPs); Information and Comment Request

AGENCY: National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Request for information and comment.

SUMMARY: The National Institute for Occupational Safety and Health (NIOSH) of the Centers for Disease Control and Prevention (CDC), as part of its mission to investigate new and emerging hazards, has initiated an evaluation of the scientific data on silver nanoparticles (AgNPs) to ascertain the potential health risks to workers and to identify gaps in knowledge so that appropriate laboratory and field research studies can be conducted. NIOSH has identified a number of relevant publications on AgNPs. This listing (*Evaluation of the scientific data on silver nanoparticles (AgNPs)*) can be found in Docket CDC-2012-0014 at <http://www.regulations.gov>.

NIOSH is requesting additional information on the following: (1) Published and unpublished reports and findings from *in vitro* and *in vivo* toxicity studies with AgNPs, (2) information on possible health effects observed in workers exposed to AgNPs, (3) information on workplaces and products in which AgNPs can be found, (4) description of work tasks and scenarios with a potential for exposure, (5) information on measurement

methods and, workplace exposure data, and (6) information on control measures (e.g., engineering controls, work practices, PPE) that are being used in workplaces where potential exposures to AgNPs occur.

DATES: Electronic or written comments must be received on or before February 19, 2013.

ADDRESSES: You may submit comments, identified by CDC-2012-0014 and docket number NIOSH-260, by any of the following methods:

- **Federal eRulemaking Portal:** <http://www.regulations.gov>. Follow the instructions for submitting comments.
- **Mail:** NIOSH Docket Office, Robert A. Taft Laboratories, MS-C34, 4676 Columbia Parkway, Cincinnati, OH 45226.

All information received in response to this notice must include the agency name and docket number (CDC-2012-0014; NIOSH-260). All relevant comments received will be posted without change to www.regulations.gov, including any personal information provided. For access to the docket to read background documents or

comments received, go to www.regulations.gov.

FOR FURTHER INFORMATION CONTACT:

Ralph Zumwalde, NIOSH, MS-C14, Robert A. Taft Laboratories, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone (513) 533-8320 or Eileen Kuempel, telephone (513) 533-8363.

Background

Nanotechnology is generally defined as the intentional manipulation of matter to form novel structures with one or more dimension or features less than 100 nanometers (nm). Nanotechnology involves a wide range of chemistries and almost unlimited types of structures that have highly unpredictable interactions with biological systems. Producing materials at the nanoscale often results in specific physicochemical characteristics that may differ from those of the bulk substance. Because of these specific characteristics the use of substances in nano-form may pose certain health risks not observed from the use of the bulk form of the substance. Nano-silver is one type of nanomaterial that may have different physical-chemical characteristics than the bulk form of silver. The National Institute for Occupational Safety and Health (NIOSH) is interested in gathering data to determine whether a health risk to workers may exist from exposure to AgNPs and if specific risk management guidance is needed to prevent exposure.

Several recently reported short-term experimental animal studies with AgNPs [Kim et al. 2008, 2009; Sung et al. 2008, 2009; Song et al. 2012] have shown consistent physiological and toxicological responses including: (1) Uptake of AgNPs to the blood and their subsequent distribution to all major organs and tissues, (2) decrements in lung function and induction of inflammatory responses, and (3) histopathology changes in the kidney and especially in the liver, in which bile duct hyperplasia was identified as the principal toxicological effect. Evidence is available from the 90-day inhalation study in Sprague-Dawley rats that AgNPs can deposit in the lung and be transported via the blood to the liver [Sung et al. 2008, 2009]. Studies also indicate that AgNPs can be transported and deposited in major organs and tissues when administered via gavage to Sprague-Dawley and F344 rats for 28 and 90 days [Kim et al. 2008, 2010]. A common feature of the systemic toxicological effects of AgNPs, irrespective of the exposure route, was the onset of histopathological effects to

the liver in exposed Sprague-Dawley and F344 rats [Sung et al. 2009; Kim et al. 2010]. High-dose animals in both studies developed bile duct hyperplasia along with some signs of hepatic necrosis. In the 90-day oral study, these effects were accompanied by changes in some clinical chemistry parameters indicative of perturbations in liver metabolism, for example, increases in serum cholesterol concentration and AP activity [Kim et al. 2010]. In the 90-day inhalation study of Sung et al. [2008, 2009] these systemic effects were accompanied by lung function deficits, the development of inflammation responses, and alveolar accumulation of macrophages [Sung et al. 2008]. In another 90-day inhalation study by the same group of researchers [Song et al. 2012], decreases in lung function and lung inflammation were observed in male rats that persisted in the high dose group at 12 weeks after cessation of exposure. In female rats, no decrease in lung function was observed, and the lung inflammation showed gradual recovery after cessation of exposure [Song et al. 2012].

Published reports on worker exposure to AgNPs are limited but indicate the potential airborne release of AgNPs during their production [Park et al. 2009; Lee et al. 2011a, b] or as an exposure resulting from the electro-refining of silver [Miller et al. 2010].

Information Needs

Additional data and information are needed to assist NIOSH in evaluating the occupational safety and health concerns of working with AgNPs. Information is particularly needed for determining the relevance of bile duct hyperplasia and hepatocellular necrosis observed in AgNP exposed rats, as well as information on: (1) Sources of AgNP exposure, (2) factors that influence worker's exposure, (3) in-place exposure control measures (e.g., engineering controls) and work practices that are effective in reducing worker exposures, and (4) appropriate measurement methods and exposure metrics for characterizing workplace exposures.

NIOSH seeks to obtain materials, including published and unpublished reports and research findings, to evaluate the possible health risks of occupational exposure to AgNPs. Examples of requested information include the following:

- (1) Identification of industries or occupations in which exposures to AgNPs may occur.
- (2) Trends in the production and use of AgNPs.

(3) Description of work tasks and scenarios with a potential for exposure to AgNPs.

(4) Workplace exposure measurement data in various types of industries and jobs.

(5) Case reports or other health information demonstrating potential health effects in workers exposed to AgNPs.

(6) Research findings from *in vitro* and *in vivo* toxicity studies, including physical-chemical characterization of AgNPs.

(7) Information on control measures (e.g., engineering controls, work practices, PPE) being taken to minimize worker exposure to AgNPs.

(8) Information on measurement methods and exposure metrics that can be used to quantify worker exposure to AgNPs including information on the limitations of those methods in quantifying exposures?

References

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- Lee JH, Mun J, Park JD, Yu IJ [2011b]. A health surveillance case study of workers who manufacture silver nanomaterials. *Nanotoxicology* DOI: 10.3109/17435390.2011.600840.
- Miller A, Drake PL, Hintz P, Habjan M [2010]. Characterizing exposures to airborne metals and nanoparticle emissions in a refinery. *Ann Occup Hyg* 54(5):504-513.
- Park J, Kwak BK, Bae E, Lee J, Kim Y, Choi K Yi J [2009]. Characterization of exposure to silver nanoparticles in a manufacturing facility. *J Nanopart Res* 11:1705-1712.
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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.

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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 oir_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