10.3109/17435390.2011.648223.
Sung JH, Ji HJ, Yoon JU, Kim DS, Song MY, Jeong J, Han BS, Han JH, Chung YH, Kim J, Kim TS, Chang HK, Lee EJ, Lee JH, Yu IJ [2008]. Lung function changes in Sprague-Dawley rats after prolonged inhalation exposure to silver nanoparticles. Inhalation Toxicol *20*:567–574.
Sung JH, Ji, JH, Park JD, Yoon, JU, Kim DS, Jeon KS, Song MY, Jeong J, Han BS, Han JE, Chung YH, Chang HK, Lee JH, Cho MH, Kelman BJ, Yu IJ [2009]. Subchronic inhalation toxicity of silver nanoparticles. Toxicol Sci *108*:452–461.

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

use authorizations (EUA) under section 564 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360bbb–3), which was amended by the Project BioShield Act of 2004 (Pub. L. 108–276). The FD&C Act permits the Commissioner to authorize the use of unapproved medical products or unapproved uses of approved medical products during an emergency declared under section 564 of the FD&C Act. The data to support issuance of an EUA must demonstrate that, based on the totality of the scientific evidence available to the Commissioner, including data from adequate and well-controlled clinical trials (if available), it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing a serious or life-threatening disease or condition (21 U.S.C. 360bbb–3(c)). Although the exact type and amount of data needed to support an EUA may vary depending on the nature of the declared emergency and the nature of the candidate product, FDA recommends that a request for consideration for an EUA include scientific evidence evaluating the product's safety and effectiveness, including the adverse event profile for diagnosis, treatment, or prevention of the serious or life-threatening disease or condition, as well as data and other information on safety, effectiveness, risks and benefits, and (to the extent available) alternatives.

Under section 564 of the FD&C Act, the FDA Commissioner may establish conditions on the authorization. Section 564(e) requires the FDA Commissioner (to the extent practicable given the circumstances of the emergency) to establish certain conditions on an authorization that the Commissioner finds necessary or appropriate to protect the public health and permits the Commissioner to establish other conditions that she finds necessary or appropriate to protect the public health. Conditions authorized by section 564(e) of the FD&C Act include, for example: Requirements for information dissemination to health care providers or authorized dispensers and product recipients; adverse event monitoring and reporting; data collection and analysis; recordkeeping and records access; restrictions on product advertising, distribution, and administration; and limitations on good manufacturing practices requirements. Some conditions, the statute specifies, are mandatory to the extent practicable for authorizations of unapproved products and discretionary for authorizations of unapproved uses of approved products. Moreover, some conditions may apply to manufacturers of an EUA product, while other conditions may apply to any person who carries out any activity for which the authorization is issued. Section 564 of the FD&C Act also gives the FDA Commissioner authority to establish other conditions on an authorization that she finds to be necessary or appropriate to protect the public health.

For purposes of estimating the annual burden of reporting (Table 1), FDA has established four categories of respondents as follows: (1) Those who file a request for FDA to issue an EUA or a substantive amendment to an EUA that has previously been issued, assuming that a requisite declaration under section 564 of the FD&C Act has been made and criteria for issuance have been met; (2) those who submit a request for FDA to review information/data (i.e., a pre-EUA package) for a candidate EUA product or a substantive amendment to an existing pre-EUA package for preparedness purposes; (3) manufacturers who carry out an activity related to an unapproved EUA product (e.g., administering product, disseminating information) who must report to FDA regarding such activity; and (4) public health authorities (e.g., State, local) who carry out an activity (e.g, administering product, disseminating information) related to an unapproved EUA product who must report to FDA regarding such activity.

In some cases, manufacturers directly submit EUA requests. Often a Federal Government entity (e.g., Center for Disease Control and Prevention, Department of Defense) requests that FDA issue an EUA and submits pre-EUA packages for FDA to review. In many of these cases, manufacturer respondents inform these requests and submissions, which are the activities that form the basis of the estimated reporting burdens. However, in some cases such as with antimicrobial products for which there are multiple generic manufacturers, the Federal Government is the sole respondent; manufacturers do not inform these requests or submissions. FDA estimates minimal burden when the Federal Government performs the relevant activities. In addition to variability based on whether there is an active manufacturer respondent, other factors also inject significant variability in estimates for annual reporting burdens. A second factor is the type of product. For example, FDA estimates greater burden for novel therapeutics than for certain unapproved uses of approved products. A third significant factor that injects variability is the type of submission. For example, FDA estimates greater burden for ''original'' EUA and pre-EUA submissions than for amendments to them, and FDA estimates minimal burden to issue an EUA when there is a previously reviewed pre-EUA package or investigational application. For purposes of estimating the reporting burden, FDA has calculated the anticipated burden on manufacturers based on the anticipated types of responses (i.e., estimated manufacturer input), types of product, and types of submission that comprise the described reporting activities.

For purposes of estimating the annual burden of recordkeeping, FDA has also calculated the anticipated burden on manufacturers and public health officials associated with administration of unapproved products authorized for emergency use, recognizing that the Federal Government will perform much of the recordkeeping related to administration of such products (*see* Table 2 of this document).

In the **Federal Register** of October 1, 2012 (77 FR 59926), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

No burden was attributed to reporting or recordkeeping for unapproved uses of approved products, since those products are already subject to approved collections of information (i.e., Adverse Experience Reporting for Biological Products is approved under 0910–0308 through November 30, 2014; Adverse Drug Experience Reporting is approved under 0910–0230 through August 31, 2015; Adverse Device Experience Reporting is approved under OMB control number 0910–0471 through May 31, 2014; Investigational New Drug (IND) Application Regulations are approved under 0910–0014 through April 30, 2015, and Investigational Device Exemption (IDE) Reporting is approved under OMB control number 0910–0078 through February 28, 2013. Any additional burden imposed by this proposed collection would be minimal.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Type of respondent	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Requests to Issue an EUA or a Substantive Amendment to an Existing EUA	9	1.33	12	33	396
FDA Review of a Pre-EUA Package or an Amendment Thereto	11	1.45	16	35	560
Manufacturers of an Unapproved EUA Product	5	1.6	8	2	16
Public Health Authorities; Unapproved EUA Product	30	3	90	2	180
Total					1,152

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Type of respondent	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Manufacturers of an Unapproved EUA Product	5	1.6	8	25	200
Public Health Authorities; Unapproved EUA Product	30	3	90	3	270
Total					470

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: *December 13, 2012.*

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2012–30513 Filed 12–18–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–1202]

Comprehensive Assessment of the Process for the Review of Device Submissions; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work for an assessment of the process for the review of medical device submissions. The assessment is part of the FDA performance commitments relating to the Medical Device User Fee Amendments of 2012 (MDUFA III), which reauthorized device user fees for fiscal years 2013–2017. The assessment is described in section V, ''Independent Assessment of Review Process Management'', of the commitment letter entitled ''MDUFA Performance Goals and Procedures'' [1] (MDUFA III Commitment Letter). The assessment will be conducted by an independent contractor in two phases. FDA is providing a period of 30 days for public comment on the statement of work before requesting proposals for the assessment.

DATES: Submit electronic or written comments by February 4, 2013.

ADDRESSES: Submit electronic comments to *http://www.regulations.gov.* Submit written comments 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. All comments received may be posted without change to *http://www.regulations.gov,* including any personal information provided. For additional information on submitting comments, see the ''Comments'' heading of the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sligar, Office of Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 3291, Silver Spring, MD 20993–0002, 301–796–9384, *Amber.Sligar@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, President Obama signed into law the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144) (FDASIA).[2] Title II of FDASIA is MDUFA III, which gives FDA the authority to collect device user fees from industry for fiscal years (FYs) 2013 to 2017. MDUFA III took effect on October 1, 2012, and will sunset in 5 years on October 1, 2017.

Device user fees were first established by Congress in 2002. Medical device companies pay fees to FDA when they register their establishment and list their devices with the Agency, whenever they submit an application or a notification to market a new medical device in the United States, and for certain other types of submissions. Under MDUFA III, FDA is authorized to collect user fees that will total approximately $595 million (plus adjustments for inflation) over 5 years. With this additional funding, FDA will be able to hire more than 200 full-time-equivalent workers over the course of MDUFA III. In exchange, FDA has committed to meet certain performance goals outlined in the MDUFA III Commitment Letter.

II. Assessment of FDA's Process for the Review of Device Submissions

Section V of the MDUFA III Commitment Letter states that FDA and the device industry will participate in a comprehensive assessment of the process for the review of device applications. The assessment will include consultation with both FDA and industry. The assessment will be conducted in two phases by a private, independent consulting firm, under

[1] *http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.*

[2] *http://www.gpo.gov/fdsys/pkg/PLAW-112publ144/pdf/PLAW-112publ144.pdf.*