Information provides funding to EPA's Exchange Network partners (states, territories, and Federally recognized Indian Tribes) to support the development of the NEIEN. The NEIEN is an Internet and- standards-based, secure information system that supports the electronic collection, exchange, and integration of data among its partners. Funding for the Grant Program has been provided through annual congressional appropriations for the EPA.

To enhance the quality and overall public benefit of the Network, EPA proposes to collect information from the NEIEN grantees about how they intend to ensure quality in their projects and the environmental outcomes and outputs from their projects. The proposed Quality Assurance Reporting Form is intended to provide a simple means for grant recipients to describe how quality will be addressed throughout their projects. The Quality Assurance Reporting Form is derived from guidelines provided in the NEIEN 2006 grant solicitation notice. As a stipulation of their award, grant recipients are to submit the form within ninety days of grant award.

Grantees are currently required to submit semi-annual progress reports as a stipulation of their award. In these reports, grantees outline project goals, activities required to meet these goals, and outputs and outcomes of activities to date. At the request of numerous grantees, we are proposing to offer the Progress Reporting Form as a vehicle for collecting information. This form is easier to complete than an unstructured narrative; it can be used as the semi-annual and final report form and the information returned will be of higher quality and comparable.

Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 1.5 hours for the Semi-Annual Report Form per response and 1 hour per Quality Assurance Form per response. Burden means the total time, effort, or financial resources expended by persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. This includes the time needed to review instructions; develop, acquire, install, and utilize technology and systems for the purposes of collecting, validating, and verifying information, processing and maintaining information, and disclosing and providing information; adjust the existing ways to comply with any previously applicable instructions and requirements that have subsequently changed; train personnel to be able to respond to a collection of information; search data sources; complete and review the collection of information; and transmit or otherwise disclose the information.

Respondents/Affected Entities: State, Tribal, and Territorial Environmental Offices receiving NEIEN grants.

Estimated Number of Respondents: 225. Frequency of Response: Twice for the Semi-Annual Report Form; once for the Quality Assurance Form.

Estimated Total Annual Hour Burden: 733. *Estimated Total Annual Cost:* $37,000 includes $0 annualized capital or O&M costs and $37,000 annual labor costs.

Are there changes in the estimates from the last approval?

Changes in the Estimates: There is no change in estimate from the last ICR renewal.

What is the next step in the process for this ICR?

EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval pursuant to 5 CFR 1320.12. At that time, EPA will issue another **Federal Register** notice pursuant to 5 CFR 1320.5(a)(1)(iv) to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB. If you have any questions about this ICR or the approval process, please contact the technical person listed under **FOR FURTHER INFORMATION CONTACT.**

Dated: June 22, 2011.

Jeffrey Wells,

Acting Director, Information Exchange & Services Division.

[FR Doc. 2011–16194 Filed 6–27–11; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS–10321]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Early Retiree Reinsurance Program (ERRP); *Use:* Under section 1102 of the Affordable Care Act and implementing regulations at 45 CFR part 149, employment-based plans that offer health benefits to early retirees and their spouses, surviving spouses and dependents are eligible under a temporary program to receive a tax-free reimbursement for the costs of certain health benefits for such individuals (the Early Retiree Reinsurance Program, or ERRP). In order to qualify, plan sponsors must submit a complete application to the U.S. Department of Health & Human Services (HHS). In order to receive reimbursement under the program, they must also submit documentation of actual costs for health care benefits, which consists of documentation of actual costs for the items and services involved, and a list of individuals to whom the documentation applies. Once HHS reviews and analyzes the information on the application, notification will be sent to the plan sponsor about its eligibility to participate in the program. Once HHS reviews and analyzes each reimbursement request, reimbursement under the program will be made to the sponsor, as appropriate. The program's funding is limited to $5 billion, and the program sunsets on January 1, 2014.

As compared with the burden estimates OMB approved on December 22, 2010, for OMB #0938–1087. There is a nominal change to burden of 1 hour, to account for the fact that sponsors have an obligation to update any incorrect or outdated information in their applications. Beyond that, there is no change to burden. The burden hours associated with reading the guidance materials related to disclosing data inaccuracies that are being included with this revised PRA submission, and with completing the Prima Facie Evidence Cover Sheet that is being

included with this revised PRA submission, were already accounted for in the PRA package OMB approved on December 22, 2010. Specially, the burden associated with completing the Prima Facie Evidence cover sheet, was included in the burden estimate for submitting a reimbursement request. The burden associated with reading the guidance paper on reporting data inaccuracies was already included in the burden estimate for disclosing data inaccuracies. *Form Number:* CMS–10321 (OCN: 0938–1087); *Frequency:* Occasionally; *Affected Public:* Private Sector: Business or other for-profits and Not-for-profit institutions: State, Local, or Tribal Governments; *Number of Respondents:* 13,200; *Number of Responses;* 71,330; *Total Annual Hours:* 1,927,575. (For policy questions regarding this collection, contact Dave Mlawsky at (410) 786–6851. For all other issues call (410) 786–1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://www.cms.hhs.gov/PaperworkReductionActof1995,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@cms.hhs.gov,* or call the Reports Clearance Office on (410) 786–1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on July 28, 2011.

OMB, Office of Information and Regulatory Affairs, *Attention:* CMS Desk Officer, *Fax Number:* (202) 395–6974, *E-mail: OIRA_submission@omb.eop.gov.*

Dated: June 23, 2011.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2011–16233 Filed 6–24–11; 4:15 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0481]

Agency Information Collection Activities; Proposed Collection; Comment Request; New Animal Drugs for Investigational Uses

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 and recordkeeping requirements for ''New Animal Drugs for Investigational Uses.''

DATES: Submit electronic or written comments on the collection of information by August 29, 2011.

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 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, when appropriate, and other forms of information technology.

New Animal Drugs for Investigational Uses—21 CFR Part 511 (OMB Control Number 0910–0117—Extension)

FDA has the authority under the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to approve new animal drugs. Section 512(j) of the FD&C Act (21 U.S.C. 360b(j)) authorizes FDA to issue regulations relating to the investigational use of new animal drugs. The regulations setting forth the conditions for investigational use of new animal drugs have been codified at part 511 (21 CFR part 511). If the new animal drug is only for tests in vitro or in laboratory research animals, the person distributing the new animal drug must maintain records showing the name and post office address of the expert or expert organization to whom it is shipped and the date, quantity, and batch or code mark of each shipment and delivery for a period of 2 years after such shipment or delivery. Before shipping a new animal drug for clinical investigations in animals, a sponsor must submit to FDA a Notice of Claimed Investigational Exemption (NCIE). The NCIE must contain, among other things, the following specific information: (1) Identity of the new animal drug, (2) labeling, (3) statement of compliance of any non-clinical laboratory studies with good laboratory practices, (4) name and address of each clinical investigator, (5) the approximate number of animals to be treated or amount of new animal drug(s) to be shipped, and (6)