for evaluating stability information were demonstrated at an FDA public meeting.

Subsequently, work has been underway in the Regulated Clinical Research Information Management technical committee in HL7 to refine the data design presented at the meeting with the goal of developing an XML standard for the exchange of product stability data based on the HL7 version 3 reference information model. HL7 is an international, open, American National Standards Institute (ANSI) accredited standards development organization that focuses on standards for the exchange of information related to health care. The Stability Data Standard was adopted by HL7 by a vote of the full membership in May 2005 and was adopted as an ANSI standard in October 2005. FDA is currently considering the adoption of the standard as a voluntary standard for transmission of stability data in new drug applications, abbreviated new drug applications, investigational new drugs, new animal drug applications, abbreviated new animal drug applications, and investigational new animal drugs.

The purpose of this pilot project is to assist in the evaluation of the data interchange standard, provide data for testing the analytical tools designed to facilitate the review of product stability data and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized product stability data.

## II. Pilot Project Description

This pilot project is part of an effort to improve the process for submitting and reviewing product stability data by increasing the consistency of the process (by establishing a uniform procedure). A consistent look and feel is expected to facilitate the review of this data. Eventually, there is the expectation that a detailed data interchange standard for the submission of product stability data will be defined based on the HL7 model. As the HL7 model was developed via a collaboration between industry and FDA, certain portions of the model may be useful for industry, but not needed in submissions to FDA. Consequently, the HL7 stability model may be adopted in whole or in part. Participants in this pilot project will have the opportunity not only to assist FDA in testing the stability data interchange standard, but will also be able to familiarize themselves with the process at an early stage of development. Only a few participants are needed for this pilot.

### *1. Initial Approach*

Because a limited number of voluntary participants are needed, the agency will use its discretion in choosing volunteers, basing this selection on a firm's experience with the preparation of product stability documents and data submissions to the different centers at FDA. During the pilot project specific technical instructions for providing the product stability data for testing will be made available to participants. Participants in the pilot project will be asked to provide the product stability data as described in the technical instructions and to provide technical feedback.

### *2. Scope*

Existing expectations for the submission of product stability data will not be waived, suspended, or modified for purposes of this pilot project. However, aside from metadata associated with the XML instance, there will be no additional data expectations beyond those data usually submitted in applications. The pilot project will test the preparation and use of the submitted product stability data.

### *3. How to Participate and Submit Comments*

Written and electronic requests to volunteer should be submitted to the docket number found in the heading of this document. In addition to requests to participate, interested persons can submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this pilot project. Two paper copies of any comments are to be submitted, except that individuals can submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. We will consider all received comments in making a determination on adopting the data interchange standard as a voluntary standard for the electronic submission of product stability data.

Dated: May 8, 2006.

**Jefrey Shuren,**

*Assistant Commissioner for Policy.*

[FR Doc. E6–7391 Filed 5–15–06; 8:45 am]

**BILLING CODE 4160–01–S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### National Institute of Environmental Health Sciences, Proposed Collection; Comment Request; The Head Off Environmental Asthma in Louisiana (HEAL) Study

**SUMMARY:** In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

**Proposed Collection**

*Title:* The Head Off Environmental Asthma in Louisiana (HEAL) Study.

*Type of Information Collection Request:* New collection.

*Need and Use of Information Collection:* The purpose of the HEAL Study is to design, implement and evaluate a case management program to intervene in asthma morbidity and examine the genetic and environmental risk factors in children in post-Katrina New Orleans. Asthma is the most common chronic disease among children in the United States; it is the number one reason children miss school and the second leading cause of emergency department visits after accidents and injuries. Asthma prevalence has been increasing dramatically, especially among minority inner-city children, where rates as high as 24% have been observed in some urban census areas. Overall rates of asthma have also increased in post-Katrina Louisiana children from 14% (2003) to 18% (2006) according to results from the Louisiana Child & Family Health Study, and may be even higher for minority and underprivileged children or children residing in certain geographical areas that were affected by post-Katrina flooding. For the HEAL Study, a school-based screening survey will be given to children (5 to 12 years of age) in the public and/or private elementary schools in New Orleans. This survey will take about 15 minutes to complete and contains questions concerning physician diagnosed asthma, asthma morbidity, healthcare, and current housing situation, as well as recent and planned changes in housing. The major purpose of the school-based survey will be to identify up to 1,000

children with moderate to severe asthma for a tailored Asthma Counselor case management intervention program and for an in depth examination of the genetic and environmental risk factors associated with asthma. We expect that about 6,000 parents or guardians will have to be interviewed in order to identify 1,000 eligible cases.

Case management will be designed to address the unique challenges presented to these children with asthma in post-Katrina New Orleans and will draw upon the prior Inner City Asthma intervention programs of the National Institutes of Health. It will also include the best components of the locally based Step Together New Orleans (Steps) and the Open Airways (American Lung Association) programs, among others. Each child will undergo a baseline assessment in the form of a questionnaire administered to their parents or guardians. This will contain questions concerning their demographics, stress, access to care, medication use, current and past symptoms, quality of life, knowledge and attitudes about asthma, and environmental exposures. The questionnaire will be administered by professional interviewers and will take about 1 hour to complete. Each child will also undergo a baseline clinical assessment for pulmonary function, allergen skin prick testing for indoor and outdoor allergens including molds, and blood draws for allergen specific IgE and genetic studies. Following the baseline assessments, the Asthma Counselors will refer the children to selected clinics for treatment and will monitor their progress by conducting periodic follow-up assessments which include a phone call with standardized questions about morbidity, treatment and exposures every two months (about 15 min each) and 2 periodic evaluations of pulmonary function. A final assessment will occur at the end of the year similar to the baseline assessment and take about 1 hour to complete.

In light of the impact of environmental exposures on asthma, a complete evaluation will also be conducted of each child's housing. This will entail the collection of environmental samples such as settled dust samples for potential allergens and triggers for asthma exacerbation (dust mite, cockroach, cat, dog, mouse, and endotoxin) and air for airborne fungal spores. The houses will be evaluated by trained technicians for the presence of mold, mildew, evidence of smoking, water leaks, disrepair, pests and other potential asthma triggers. The ultimate goal of this study is to develop case management and environmental intervention strategies for this population of post-Katrina children to reduce their asthma morbidity and improve their quality of life. These strategies could potentially be used to intervene in other future disasters similar to hurricane Katrina.

*Estimated Number of Respondents:* The estimated number of respondents is 40,000 which includes the parents or guardians of 1,000 children enrolled in the case management intervention and environmental assessment programs.

*Affected Public:* Individuals or households.

*Type of Respondents:* Children with asthma 5 to 12 years of age or their parents or guardians.

The annual reporting burden is as follows:

*Estimated Number of Responses per Respondent:* The table below shows the estimated number of responses per respondent per activity over the next two years.

*Average Burden Hours per Response:* 0.36; and

*Estimated Total Annual Burden Hours Requested:* 20,500 over 2 years.

The average annual burden hours requested is 10,250. The annualized cost to respondents is estimated at $7.20 (assuming $20 hourly wage). There are no Capital Costs to report. There are no Operating or Maintenance Costs to report.

| Activity | Estimated number of respondents | Estimated responses per respondent | Average burden hours per response | Estimated total burden hours requested |
|---|---|---|---|---|
| School-based eligibility screening | 40,000 | 1 | 0.25 | 10,000 |
| Enrollment interview | 6,000 | 1 | 0.5 | 3,000 |
| Baseline QX assessment | 1,000 | 1 | 1.25 | 1,250 |
| Baseline Medical assessment | 1,000 | 1 | 2 | 2,000 |
| Phone follow-up | 1,000 | 6 | 0.25 | 1,500 |
| Pulmonary function assessment | 1,000 | 2 | 1 | 2,000 |
| Yearly follow-up | 1,000 | 1 | 2 | 1,000 |
| Total | | | | 20,750 |

*Request for comments:* Written comments and/or suggestions from the public and affected agencies are invited on one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency'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 those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Patricia Chulada, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541–7736 or e-mail your request, including your address to *chulada@niehs.nih.gov.*

*Comments due date:* Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

Dated: May 4, 2006.

**Richard A. Freed,**

*Associate Director for Management, NIEHS.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

### Government-Owned Inventions; Availability for Licensing

**AGENCY:** National Institutes of Health, Public Health Service, HHS.