These data collections are part of the BSF evaluation, which is an important opportunity to learn if well-designed interventions can help low-income couples develop the knowledge and relationship skills that research has shown are associated with healthy marriages. BSF programs will provide instruction and support to improve marriage and relationship skills and enhance couples' understanding of marriage. In addition, BSF programs will provide links to a variety of other services that could help couples sustain a healthy relationship (e.g., employment assistance). The BSF evaluation uses an experimental design that randomly assigns couples who volunteer to participate in BSF programs to a program or to a control group.

The BSF evaluation has two parts, an implementation study and an impact study. For the implementation study, the BSF evaluation will use the interview and focus-group protocols to document how the programs worked and the experiences of staff and couples enrolled. For the impact study, the BSF evaluation will use telephone surveys to determine whether the BSF programs helped couples form healthier marriages.

Respondents: for the implementation study, respondents will be BSF program managers and staff, couples who participated in the BSF group sessions, and couples who dropped out of the program or never participated in the BSF groups. Information from staff will be obtained in face-to-face interviews. Information from participating couples will be collected in focus groups. Non-participating couples and couples who dropped out of the program will be interviewed by phone. For the impact study, the respondents for the 15-month survey will be all couples in the BSF evaluation. They will be interviewed by telephone. Both types of information collection will take place over about a 24-month period.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Implementation Study				
Staff interview protocol	126	1	1.5	189
Focus group protocol	70	1	1.5	105
Telephone interview protocol (non-participants/dropouts)	84	1	.17	14
Impact Study				
15-month Survey (females)	1,434	1	.91	1,305
15-month Survey (males)	1,434	1	.83	1,190
Estimated Total Annual Burden Hours				2,803

Additional Information: Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov.*

OMB Comment: OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Attn: Desk Officer for ACF, E-mail address: *Katherine_T._Astrich@omb.eop.gov.*

Dated: May 11, 2006.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 06–4584 Filed 5–15–06; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0181]

Product Stability Data; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is seeking volunteers to participate in a pilot project involving the testing of a Health Level 7 (HL7) data interchange standard for the submission of product stability data to FDA to facilitate the review of this data. Using the data interchange standards and the analytical tools will allow consistent data presentation to the agency and allow a reviewer to more efficiently and consistently display and evaluate product stability data submitted in electronic format.

DATES: Submit written or electronic requests to participate in the pilot project by July 17, 2006. Comments on this pilot project can be submitted at any time.

ADDRESSES: Submit written requests to participate to Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.fda.gov/dockets/ecomments.*

FOR FURTHER INFORMATION CONTACT: Norman Schmuff, Food and Drug Administration, Center for Drug Evaluation and Research, 10903 New Hampshire Ave., Bldg. 22, rm. 2472,Silver Spring, MD 20993–0002, *norman.schmuff@fda.hhs.gov* or Norman Gregory, Food and Drug Administration, Center for Veterinary Medicine (HFV–143), Rockville, MD 20857, *norman.gregory@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I . Background

Applicants provide product stability information in marketing applications and other submissions to the various centers of FDA. This information is currently provided in paper documents or as a series of portable document format (PDF) files. In January 2001, a format for presenting product stability data in extensible markup language (XML) and a prototype of a review tool

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