SEND was developed by the Clinical Data Interchange Standards Consortium's (CDISC's) SEND Team. CDISC is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition and submission of clinical trial data and metadata for medical and biopharmaceutical product development (*http://www.cdisc.org*[1]). CDISC is currently facilitating and testing the extension of the same SEND standard for nonclinical toxicology data. Where possible, the standards developed for clinical datasets and metadata, as described in the overall Study Data Tabulation Model (SDTM), are being used to develop a standardized dataset format for nonclinical studies.

Recently, the Center for Drug Evaluation and Research (CDER) completed a pilot project (phase 1) using the SEND format in sample toxicology datasets, that is, outside of a regulatory setting (68 FR 3885, January 27, 2003). The phase 1 CDER pilot also evaluated data validation and analysis tools specifically designed to validate datasets according to the current SEND standard and to enable a reviewer to display and evaluate data efficiently from animal toxicity studies submitted in the SEND format. The phase 1 pilot resulted in the development of a SEND Implementation Guide (SENDIG) describing the process for formatting data from single- and repeat-dose animal toxicity and carcinogenicity studies for submission purposes. Following the phase 1 pilot, CDER announced a second pilot (phase 2) to test SEND formatted datasets in a regulatory setting (72 FR 56363, October 3, 2007). To support the new CDER pilot, the SENDIG has been updated to ensure the harmonized implementation of the CDISC SDTM and SEND models. The updated guide can be found at *http://www.cdisc.org*.

CVM currently receives margin of safety and nonclinical toxicology study data in paper, portable document format (PDF), and other electronic formats. The lack of uniformity in the formats used by sponsors to submit data, in addition to the inconsistent use of terminology across submissions, complicates the agency's efforts to validate, display, and evaluate the data using modern, computer-based review and analysis tools. As part of FDA's effort to modernize its information technology systems and improve efficiency, CVM is planning to transition to a true electronic data format for submission of study data for regulatory review.

[1] FDA has verified the Web site address, but FDA is not responsible for any subsequent changes to the Web site address after this document publishes in the **Federal Register**.

II. Pilot Project Description

This pilot is intended to help CVM evaluate the adequacy of the current SEND format (SAS transport files, XPT version 5) in accommodating margin of safety and nonclinical toxicology study data submitted to the Center. As part of this evaluation and in anticipation of FDA receiving datasets for regulatory review, the CDISC SEND Team, in collaboration with FDA and available pilot participants, will first update the SENDIG as needed to include veterinary-specific data elements and terms.

As experience from the ongoing pilot is gained with various types of margin of safety and nonclinical toxicology study data, CVM expects to recommend new technical specifications for margin of safety and toxicology studies as part of a continuing process of transitioning from paper-based submissions to the submission of study data by electronic means.

III. Participation

CVM is seeking a limited number of sponsors (approximately five to eight, but no more than eight) to participate in this pilot. Because a limited group of voluntary participants is needed, CVM will use its discretion in choosing volunteers, based on their experience with datasets previously submitted to CVM. The duration of the pilot is expected to be approximately 3 years, but it may be extended as needed. A familiarity with SEND (e.g., from involvement in the CDER pilot) would benefit participants but is not necessary for participation in the project. A participant should be willing to provide the same study data in both paper format and SEND electronic format using SAS transport files (XPT version 5). The pilot provides the best opportunity to compare and evaluate the same data available in paper and SEND formats in order to test the accuracy and reliability of the SEND format.

For the purposes of this pilot, study reports from margin of safety and nonclinical toxicology study data will be requested for submission. We anticipate that a successful pilot, including the implementation of any needed changes to the SENDIG and/or the data validation, viewing, and analysis tools, will allow CVM to accept specific types of margin of safety and nonclinical toxicology study data electronically based on the SEND format.

Requests to participate in the pilot project should be submitted to the Division of Dockets Management (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

Under current FDA regulations, applicants must provide evidence to establish safety and effectiveness as part of their NADA (21 CFR 514.1(b)(8)). Participation in this pilot program will not exempt participants from compliance with applicable requirements for the submission of evidence to establish safety and effectiveness.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) electronic or written comments regarding this pilot project. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: December 4, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9–29419 Filed 12–9–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID: FEMA–2009–0001]

Agency Information Collection Activities: Proposed Collection; Comment Request, 1660–0105; Community Preparedness and Participation Survey

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice; 60-day notice and request for comments; revision of a currently approved information collection; OMB No. 1660–0105; 088–0–2, Household Preparedness Telephone Survey.

SUMMARY: The Federal Emergency Management Agency, as part of its continuing effort to reduce paperwork and respondent burden, invites the

general public and other Federal agencies to take this opportunity to comment on a proposed extension, without change, of a currently approved information collection. In accordance with the Paperwork Reduction Act of 1995, this Notice seeks comments concerning the Community Preparedness and Participation Survey, a telephone survey that collects preparedness information from the general population.

DATES: Comments must be submitted on or before February 8, 2010.

ADDRESSES: To avoid duplicate submissions to the docket, please use only one of the following means to submit comments:

(1) *Online.* Submit comments at *http://www.regulations.gov* under docket ID FEMA–2009–0001. Follow the instructions for submitting comments.

(2) *Mail.* Submit written comments to Office of Chief Counsel, Regulation and Policy Team, DHS/FEMA, 500 C Street, SW., Room 835, WASH, DC 20472–3100.

(3) *Facsimile.* Submit comments to (703) 483–2999.

(4) *E-mail.* Submit comments to *FEMA-POLICY@dhs.gov.* Include docket ID FEMA–2009–0001 in the subject line.

All submissions received must include the agency name and docket ID. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to read the Privacy Act notice that is available on the Privacy and Use Notice link on the Administration Navigation Bar of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Contact Jenelle Gabriele, Program Specialist, Community Preparedness Division at 202–786–9463 for additional information. You may contact the Records Management Branch for copies of the proposed collection of information at facsimile number (202) 646–3347 or e-mail address: *FEMA-Information-Collections@dhs.gov.*

SUPPLEMENTARY INFORMATION: This survey will allow the Federal Emergency Management Agency (FEMA) to collect information that reports the state of citizen preparedness in the United States. FEMA's Community Preparedness Division administers Citizen Corps, an initiative launched by President George W. Bush in Executive Order 13254 in January 2002. Citizen Corps' mission is to bring together government and community leaders to involve citizens in all-hazards emergency preparedness and resilience. To evaluate the Nation's progress on personal preparedness, FEMA's Community Preparedness Division conducts National surveys to measure the public's knowledge, attitudes, and behaviors relative to preparing for a range of hazards. This information collection enables Citizen Corps Councils and other community based organizations to improve upon their strategies to enhance preparedness programs and disaster response.

Collection of Information

Title: Community Preparedness and Participation Survey.

Type of Information Collection: Revision of a currently approved information collection.

OMB Number: OMB No. 1660–0105.

Form Titles and Numbers: FEMA Form 088–0–2, Household Preparedness Telephone Survey.

Abstract: FEMA's Community Preparedness Division would like to renew a currently approved collection to evaluate the state of preparedness nationally. The Community Preparedness Division analyzes the data collected through this telephone survey of the public to identify progress and gaps in citizen and community preparedness and participation. This information is used by the Community Preparedness Division, and Citizen Corps Councils to tailor awareness and recruitment campaigns, messaging and public information efforts, and strategic planning initiatives to more effectively improve the state of citizen preparedness and participation across the country.

Affected Public: Individuals or households.

Estimated Total Annual Burden Hours: 3,247 hours.

TABLE A.12—ESTIMATED ANNUALIZED BURDEN HOURS AND COSTS

Type of respondent	Form name/form number	Number of respondents	Number of responses per respondent	Total Number of responses	Avg. burden per response (in hours)	Total annual burden (in hours)	Avg. hourly wage rate*	Total annual respondent cost
Individuals or households.	Household Preparedness Telephone Survey/ FEMA Form 088–0–2.	9,750	1	9,750	20 minutes (.333 hours).	3,247	$21.80	$70,784.60
Total	.....	9,750	.....	.....	.....	3,247	.....	70,784.60

Estimated Cost: None.

Comments

Comments may be submitted as indicated in the **ADDRESSES** caption above. Comments are solicited to (a) evaluate whether the proposed data collection is necessary for the proper performance of the agency, including whether the information shall have practical utility; (b) evaluate 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; (c) enhance the quality, utility, and clarity of the information to be collected; and (d) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Dated: December 4, 2009.

Samuel C. Smith,

Acting Director, Records Management Division, Office of Management, Federal Emergency Management Agency, Department of Homeland Security.

[FR Doc. E9–29448 Filed 12–9–09; 8:45 am]

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