from animal studies submitted in the SEND format. The 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). The phase 2 pilot was aimed at evaluating animal toxicity data submitted in SEND format in a regulatory setting by comparing SEND-formatted data provided electronically as SAS transport file (XPT version 5) datasets with data provided in PDF.

CBER currently receives nonclinical study data in paper, 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 CBER'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, CBER is planning to transition to an electronic data format for submission of study data for regulatory review.

II. Pilot Project Description

This pilot is intended to help CBER evaluate the adequacy of the current SEND format (SAS transport files, XPT version 5) in accommodating nonclinical 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 update the SENDIG as needed to include biologic-specific data elements and terms.

III. Requests for Participation

Requests to participate in the SEND pilot are to be identified with the docket number found in brackets in the heading of this document. You should include the following information in your request: Contact name, contact phone number, email address, name of the establishment, address, and license number. Once requests for participation are received, FDA will contact interested establishments to discuss the pilot program. CBER is seeking a limited number of sponsors (approximately three to five, but no more than six) to participate in this pilot. The duration of the pilot is expected to be approximately 12 months but may be extended as needed. A familiarity with SEND would benefit participants but is not required for participation in the project. Participants should be willing to provide the same nonclinical study data in both paper format and SEND electronic format using SAS transport files (XPT version 5). Participation in this pilot will be outside the regulatory pathway and as such will not be used to make regulatory decisions.

We anticipate that a successful pilot program, including the implementation of any needed changes to the SENDIG and/or data validation, viewing and analysis tools, will allow CBER to accept specific types of nonclinical study data electronically based on the SEND format.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4785 Filed 2–28–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Food Labeling Workshop; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

The Food and Drug Administration (FDA), Office of Regulatory Affairs (ORA), Dallas District Office (DALDO), in collaboration with Oklahoma State University (OSU), Robert M. Kerr Food & Agricultural Products Center (FAPC), is announcing a public workshop entitled ''Food Labeling Workshop.'' This public workshop is intended to provide information about FDA food labeling regulations and other related subjects to the regulated industry, particularly small businesses and startups.

Date and Time: This public workshop will be held on April 24 and 25, 2012, from 8 a.m. to 5 p.m.

Location: This public workshop will be held at FAPC, OSU, 148 FAPC, Stillwater, OK 74078–6055.

Contact: David Arvelo, Office of Regulatory Affairs, Food and Drug Administration, Southwest Regional Office, 4040 North Central Expressway, Suite 900, Dallas, TX 75204, 214–253–4952, FAX: 214–253–4970, email: *david.arvelo@fda.hhs.gov*.

For information on accommodation options, contact conference coordinators Karen Smith or Andrea Graves at FAPC, OSU, 148 FAPC, Stillwater, OK 74078–6055, 405–744–6071, FAX: 405–744–6313, or email: *karenl.smith@okstate.edu* or *andrea.graves@okstate.edu*. More information is also available online at *http://www.fapc.biz/foodlabeling.html*. (FDA has verified the Web site address, but we are not responsible for any subsequent changes to the Web site after this document publishes in the **Federal Register**.)

Registration: You are encouraged to register by April 10, 2012. The workshop has a $400 registration fee to cover the cost of facilities, materials, lunch, and breaks. Seats are limited; please submit your registration as soon as possible. Workshop space will be filled in order of receipt of registration. Those accepted into the workshop will receive confirmation. Registration will close after the workshop is filled. Registration at the site is not guaranteed but may be possible on a space available basis on the day of the public workshop beginning at 8 a.m. The cost of registration at the site is $400 payable to FAPC. There are no registration fees for FDA employees.

If you need special accommodations due to a disability, please contact Karen Smith (see *Contact*) at least 7 days in advance.

Registration Form Instructions: To register, please complete the online registration form at *http://www.fapc.biz/forms/foodlabeling.htm*.

Transcripts: Transcripts of the public workshop will not be available due to the format of this workshop. Course handouts may be requested after the date of the public workshop through the contact persons (see *Contact*) at cost plus shipping.

SUPPLEMENTARY INFORMATION: This public workshop is being held in response to the large volume of food labeling inquiries from small food manufacturers and startups originating from the area covered by the FDA DALDO. FDA DALDO presents this workshop to help achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393), which include working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. This is consistent with the purposes of ORA's Small Business Representative Program, which are in part to respond to industry inquiries, develop educational materials, and sponsor workshops and conferences to provide firms, particularly small businesses, with firsthand working knowledge of FDA's requirements and

compliance policies. This workshop is also consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

The goal of this public workshop is to present information that will enable manufacturers and regulated industry to better comply with labeling requirements, especially in light of growing concerns about obesity and food allergens. Information presented will be based on Agency position as articulated through regulation, compliance policy guides, and information previously made available to the public. Topics to be discussed at the workshop include: (1) Mandatory label elements, (2) the Food Allergen Labeling and Consumer Protection Act of 2004, (3) nutrition labeling requirements, (4) health and nutrition claims, and (5) special labeling issues, such as exemptions. FDA expects that participation in this public workshop will provide regulated industry with greater understanding of the Agency's regulatory and policy perspectives on food labeling and increase voluntary compliance with labeling requirements.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4782 Filed 2–28–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

In compliance with the requirement for opportunity for public comment on proposed data collection projects (section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

Comments are invited on: (a) The proposed collection of information for the proper performance of the functions of the Agency; (b) the accuracy of the Agency's estimate of the burden of the proposed collection of information; (c) ways to enhance 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.

Proposed Project: Maternal, Infant and Early Childhood Home Visiting Program FY 2012 Competitive Funding Opportunity Announcement (OMB No. 0915–xxxx)—[New]

On March 23, 2010, the President signed into law the Patient Protection and Affordable Care Act (the Act). Section 2951 of the Act amended Title V of the Social Security Act by adding a new section, 511, which authorized the creation of the Maternal, Infant, and Early Childhood Home Visiting Program, (*http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h3590enr.txt.pdf,* pages 216–225). The Act responds to the diverse needs of children and families in communities at risk and provides an unprecedented opportunity for collaboration and partnership at the Federal, State, and community levels to improve health and development outcomes for at risk children through evidence-based home visiting programs.

Under this program, a funding opportunity announcement for formula-based funding for States was issued in June 2011. The same level of funding, $125,000,000, was made available to States according to the same formula as in FY 2010. These two-year grants were awarded to support States in implementing their Updated State Plans that were submitted during the summer of 2011.

Additionally, a competitive Funding Opportunity Announcement (FOA) was issued in June 2011 to allow interested States to apply for one of two possible grants: Development Grants and Expansion Grants. Development Grants were intended to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. Expansion Grants were intended to recognize states and jurisdictions that had already made significant progress towards a high-quality home visiting program or embedding their home visiting program into a comprehensive, high-quality early childhood system. Among eligible applicants to the competitive grant program, 13 States were awarded Development Grants and nine States were awarded Expansion Grants. Currently, the 54 States and eligible jurisdictions participating in the formula-funded program have begun implementing their State Home Visiting Plans. Because the FY 2011 grants were for two-years, no additional FOA will be issued this year for the formula program, but the State grantees will be completing non-competing progress reports in order to secure the release of their FY 2012 allocations. The 22 States that received competitive grant funding have also begun to carry out their proposed programs, integrating them with their formula-based programming. These competitive grants are for two years (Development Grants) and four years (Expansion Grants) respectively, and those grantees will also be completing non-competitive progress reports for FY 2012.

The Maternal, Infant, and Early Childhood Home Visiting Program intends to make an additional $84,484,397 available for Development and Expansion Grants in FY 2012. With the concurrence of the Secretary, ten more Expansion Grants, totaling $71,359,043, will be awarded (by rank order) from among high-ranking applicants under the FY 2011 announcement. The FY 2012 competitive FOA will announce approximately $12,000,000 for new Development Grants. The intent of these Development Grants is identical to that announced in FY 2011, which is to support States and jurisdictions with modest evidence-based home visiting programs to expand the depth and scope of these efforts, with the intent to develop the infrastructure and capacity needed to seek an Expansion Grant in the future. It is anticipated that there will be awarded between four and eight Development Grants. The total grant award may range between $1 million to $3 million annually. Applicants may apply for a ceiling amount of up to $3 million per year. The project period is two (2) years.

The annual estimate of burden is as follows: