a packet containing beads—it is important to have reasonable assurance that the patient will be able to swallow the beads (uncrushed) with the food with which the beads are mixed without stimulating the urge to chew. Additional assurances may be needed when the label also includes specific language concerning alternate administration via an enteral feeding tube.

The recommendations in this guidance are based on literature on chewing and swallowing particle size and on Agency experience with NDAs and ANDAs submitted for these dosage forms. This guidance provides the following information related to drug products labeled for sprinkle: Appropriate maximum size for the beads, special considerations for sprinkle drug products that include language in labeling concerning alternate administration via an enteral feeding tube, and bioavailability (BA) or bioequivalence (BE) recommendations.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on the size of beads in drug products labeled for sprinkle. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments 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.

III. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). Information submitted in an NDA, ANDA, or BLA supporting the appropriate size for beads in drug products that are labeled to be administered via sprinkling, including related BA and BE studies, is approved by OMB under control number 0910–0001 for NDAs and ANDAs and control number 0910–0338 for BLAs.

IV. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov*.

Dated: February 23, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–4784 Filed 2–28–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0130]

Electronic Submission of Nonclinical Study Data; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) is announcing an invitation to participate in a pilot evaluation program to test the electronic submission of nonclinical study data using the Standard for Exchange of Nonclinical Data (SEND), a new electronic data standard format, which can be used to support review activity. Participation in the pilot program is open to all sponsors. The pilot program is intended to provide industry and CBER regulatory review staff the opportunity to evaluate SEND and determine if it facilitates the submission process of nonclinical study data related to investigational new drug applications (INDs).

DATES: Submit either electronic or written requests for participation in this pilot program by May 29, 2012.

ADDRESSES: Submit electronic requests to participate in the pilot and comments regarding the project to *http://www.regulations.gov*. Submit written requests and comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Amy Malla, Center for Biologics Evaluation and Research (HFM–25), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6085, email: *Amy.Malla@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates certain biological products and is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness and timely delivery of these products to patients. Further, CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing CBER staff and industry with improved processes. In support of this goal, CBER has participated in the development of the Clinical Data Interchange Standards Consortium (CDISC) SEND, a data model initially developed for nonclinical data from animal studies submitted in support of applications for approval of human drugs. This pilot is designed to test the ability of SEND to support the review of nonclinical study data submitted to CBER. The ultimate goal of the pilot is to replace the existing paper and portable document format (PDF)-based listings of nonclinical study data.

SEND was developed by the CDISC SEND Team. CDISC is an open, multidisciplinary, nonprofit organization that has established worldwide industry standards to support the electronic acquisition, exchange, submission, and archiving of clinical trial data and metadata for medical and biopharmaceutical product development (*http://www.cdisc.org*). 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 format for nonclinical studies.

Recently, CBER has adopted a standard for clinical study data based on the CDISC SDTM standard. FDA believes the use of standardized SEND datasets, together with new and better analysis tools, will enhance CBER's review and evaluation of nonclinical data.

The Center for Drug Evaluation and Research (CDER) completed a pilot project (phase 1) using the SEND format in sample nonclinical 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 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]

BILLING CODE 4160–01–P

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