and B. Roerig & Co., then a division of Pfizer, that contained hydroxyzine hydrochloride and hydroxyzine pamoate (44 FR 6780, February 2, 1979) (the February 1979 **Federal Register** notice). Although some indications for these products were found to be supported by adequate and well-controlled clinical studies, other indications were determined to be lacking substantial evidence of effectiveness (Id.). The February 1979 **Federal Register** notice offered an opportunity for hearing with respect to the indications found to be lacking substantial evidence of effectiveness, as well as with respect to any issues relating to the legal status of the drug products subject to it.

In response to the February 1979 **Federal Register** notice, Pfizer requested a hearing. No other companies requested a hearing. On November 22, 2010, FDA sent a letter to Pfizer to determine whether Pfizer remained interested in pursuing its hearing request. On December 22, 2010, Pfizer responded by withdrawing its hearing request. There are no longer outstanding hearing requests pertaining to Docket No. FDA–1978–N–0441 (formerly 78N–0324). Therefore, shipment in interstate commerce of any product identified in this docket, or any IRS product, that is not the subject of an approved NDA or ANDA is unlawful as of the effective date of this notice. This notice is not applicable to OTC products that comply with an OTC monograph (21 CFR 310.6(f)). Any person who wishes to determine whether a specific product is covered by this notice should write to the Center for Drug Evaluation and Research (see ADDRESSES).

III. Discontinued Products

Some firms may have previously discontinued the manufacturing or distribution of products covered by this notice without removing them from the listing of their products under section 510(j) of the FD&C Act (21 U.S.C. 360(j)). Other firms may discontinue manufacturing or marketing listed products in response to this notice. Firms that wish to notify the Agency of product discontinuation should send a letter, signed by the firm's chief executive officer, fully identifying the discontinued product(s), including National Drug Code (NDC) number(s), and stating that the product(s) have been discontinued. The letter should be sent to Pamela Lee (see **ADDRESSES**).

Firms should also update the listing of their products under section 510(j) of the FD&C Act to reflect discontinuation of unapproved products. FDA plans to rely on its existing records, including drug listing records or other available information, when it targets violations for enforcement action. Firms should be aware that after the effective date of this notice, FDA intends to take enforcement action without further notice against any firm that manufactures or ships in interstate commerce any unapproved product covered by this notice.

IV. Reformulated Products

FDA cautions firms against reformulating products into OTC products or different unapproved new drugs that are marketed under the same name or substantially the same name (including a new name that contains the old name). Reformulated products marketed under a name previously identified with a different active ingredient or combination of active ingredients have the potential to confuse health care practitioners and harm patients.

This notice is issued under the FD&C Act (sections 502 and 505 (21 U.S.C. 352 and 355)), and under authority delegated to the Deputy Commissioner for Policy under section 1410.10 of the FDA Staff Manual Guide.

Dated: February 17, 2012.

David Dorsey,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2012–4781 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–2011–D–0024]

Guidance for Industry on Size of Beads in Drug Products Labeled for Sprinkle; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Size of Beads in Drug Products Labeled for Sprinkle.'' This guidance provides applicants preparing or submitting new drug applications (NDAs), abbreviated new drug applications (ANDAs), and biologics licensing applications (BLAs) the Center for Drug Evaluation and Research's (CDER's) current thinking on appropriate size ranges for beads in drug products that are labeled to be administered via sprinkling (e.g., capsules or packets containing beads).

In the **Federal Register** of January 19, 2011 (76 FR 3144), FDA announced the availability of the draft version of this guidance. The public comment period closed on April 19, 2011. A number of comments were received from the public, all of which the Agency considered carefully as it finalized the guidance and made appropriate changes.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written 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: Laurie Muldowney, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, rm. 4154, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–1571.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Size of Beads in Drug Products Labeled for Sprinkle.'' This guidance provides applicants preparing or submitting NDAs, ANDAs, and BLAs CDER's current thinking on appropriate size ranges for beads in drug products that are labeled to be administered via sprinkling (e.g., capsules or packets containing beads).

Certain drug products that contain beads within a capsule indicate in the labeling that the capsule can be broken and the internal beads can be sprinkled on soft foods and swallowed without chewing as an alternative administration technique. This is particularly common with drug products designed to have extended- or delayed-release characteristics (i.e., the beads are manufactured to release the drug product at different rates). To make certain that the intended product performance is achieved—whether from a capsule that has been broken or from

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