and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 25, 2007 (72 FR 20555), the agency announced that the proposed information collection had been submitted to OMB for review and clearance under 44 U.S.C. 3507. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. OMB has now approved the information collection and has assigned OMB control number 0910–0302. The approval expires on August 31, 2010. A copy of the supporting statement for this information collection is available on the Internet at *http://www.fda.gov/ohrms/dockets*.

Dated: September 26, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E7–19457 Filed 10–2–07; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Nominations for Membership on the Board of Directors of the Reagan-Udall Foundation From Consumer Advocacy Groups, Professional Scientific and Medical Societies, and Industry Trade Organizations

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the opportunity for patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations to nominate candidates to serve on the Board of Directors (the Board) of a new non-profit foundation, the Reagan-Udall Foundation for the Food and Drug Administration (the Foundation). The Foundation will be dedicated to modernizing medical, veterinary, food, food ingredient, and cosmetic product development, accelerating innovation, and enhancing product safety.

DATES: Submit written or electronic nominations on or before October 15, 2007.

ADDRESSES: Submit written nominations either by fax to Lisa Rovin or Nancy Stanisic at 301–443–9718 or by e-mail to *Reagan-Udall-Board@FDA.HHS.GOV*.

FOR FURTHER INFORMATION CONTACT:

Lisa Rovin, Office of Policy and Planning (HF–11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1443; or

Nancy Stanisic, Office of Critical Path Programs (HF–18), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1660.

SUPPLEMENTARY INFORMATION:

I. Background

On September 27, 2007, the President signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA). The law reauthorizes the Prescription Drug User Fee Act, the Medical Device User Fee Act, the Best Pharmaceuticals for Children Act, and the Pediatric Research Equity Act of 2007, and enacts the Pediatric Medical Device Safety and Improvement Act of 2007 as well as additional requirements and authorities for FDA. Title VI of FDAAA creates the Foundation. The purpose of the Foundation is to ''advance the mission of the Food and Drug Administration to modernize medical, veterinary, food, food ingredient, and cosmetic product development, accelerate innovation, and enhance product safety.''

The duties of the Foundation include the identification of unmet needs in the development, manufacture, and evaluation (including postmarket evaluation) of the safety and effectiveness of FDA-regulated products, and the establishment of scientific and other projects and programs to meet those needs.

II. Criteria for Board Membership

The statute mandates a 14-member Board of Directors, composed of the following:

- Four representatives of the general pharmaceutical, device, food, cosmetic, and biotechnology industries;
- Three representatives of academic research organizations;
- Two representatives of patient or consumer advocacy organizations;
- One representative of health care providers; and
- Four at-large representatives with expertise or experience relevant to the purpose of the Foundation.

The Board must include individuals with expertise in areas including the sciences of developing, manufacturing, and evaluating the safety and effectiveness of devices, including diagnostics, biological products, and drugs, and the safety of food, food ingredients, and cosmetics.

The Foundation's Board will be responsible for governing the organization and ensuring that it succeeds in its mission. To that end, the Board members will oversee the mission and operations of the Foundation, including: Approving programs and monitoring their effectiveness, coordinating Foundation activities with federal research programs, awarding grants, and ensuring financial solvency and raising resources.

The initial Board is to be appointed no later than 30 days after enactment, September 27, 2007, by the ex officio board members designated in the statute: The Commissioner of Food and Drugs, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, and the Director of the Agency for Healthcare Research and Quality. Nine Board members are to be appointed from a list of candidates provided by the National Academy of Sciences. Five Board members are to be appointed from lists of candidates provided by ''patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations.''

III. Process and Criteria for Nominations

To facilitate nomination of candidates from patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations, FDA is publishing this notice and accepting nominations by fax or e-mail submission (see **ADDRESSES**). We welcome nominations from any such organization, and are not limiting the number of nominations each organization may submit. We will accept joint nominations from multiple organizations.

Each nomination should include the following information:

(1) Name, affiliation, and contact information for each nominating organization, and a statement indicating to which of the following categories the nominating organization belongs: Patient and consumer advocacy groups, professional scientific and medical societies, and industry trade organizations.

(2) Name, title, affiliation (if any), resume or curriculum vitae, and contact information for each nominee. In addition, please include no more than one paragraph describing the individual's qualifications in relation to the mission of the Foundation and the statutory criteria for Board membership, described in section II of this document. A nominee may qualify in more than one of the statutory categories for Board membership; please list all categories for which each nominee qualifies.

IV. Electronic Access

Persons with access to the Internet may obtain the FDAAA statute at: *http://www.fda.gov/oc/initiatives/advance/fdaaa.html*.

Dated: September 27, 2007.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 07–4882 Filed 9–28–07; 1:26 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007N–0343]

Electronic Nonclinical Study Data Submission; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Center for Drug Evaluation and Research (CDER) is seeking sponsors interested in participating in a pilot project to test, in a regulatory setting, the electronic submission of nonclinical study data using the Standard for Exchange of Nonclinical Data (SEND). The purpose of this pilot is to test the ability of a new electronic data format to support nonclinical review activity. The pilot also will involve a collaboration of FDA, available pilot participants, and the SEND Consortium to update and create a new draft SEND implementation guide. FDA anticipates that a successful pilot will enable CDER to routinely accept nonclinical study data electronically in SEND format, instead of paper or portable document format (PDF), in investigational new drug applications (INDs), new drug applications (NDAs), and biologics licensing applications (BLAs).

DATES: Submit written or electronic requests to participate in the pilot project by January 2, 2008. General comments on the pilot project are welcome at any time.

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

FOR FURTHER INFORMATION CONTACT: Bobbie Witczak, Food and Drug Administration, 5600 Fishers Lane HFD–070, Rockville, MD 20857, 301–827–3938.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing an opportunity to participate in a 3-year pilot project in a regulatory setting being conducted by CDER involving the ongoing testing of SEND, a nonclinical data model developed by the Clinical Data Interchange Standards Consortium (CDISC) . The ultimate goal of the pilot is to replace the existing paper/PDF-based listings of nonclinical study data.

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*). CDISC is currently facilitating the extension of the same standard for nonclinical data, termed SEND, through the efforts of the SEND Consortium. 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.

Under current regulations, applicants must provide tabulated nonclinical data from animal toxicity studies as part of NDA (21 CFR 314.50) and IND (21 CFR 312.23) applications. In a guidance for industry titled ''Providing Regulatory Submissions in Electronic Format—Human Pharmaceutical Product Application and Related Submissions Using the eCTD Specifications,'' FDA makes recommendations about how to submit documents in electronic format to INDs, BLAs, and NDAs using the electronic common technical document (eCTD) specifications. CDER currently receives nonclinical study data either on paper or as electronic PDF files. These formats do not support the agency's ability to easily receive, validate, display, or 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, the agency is planning to transition from the traditional paper/PDF formats to a true electronic data format for submission of nonclinical data for regulatory review.

Recently, CDER has adopted a standard for clinical study data based on the CDISC SDTM standard. In addition, CDER entered into a CRADA (cooperative research and development agreement) with PharmQuest Corporation, Inc., for the development of data validation, viewing, and analysis tools to evaluate standardized nonclinical datasets based on SEND. The FDA believes the use of standardized SEND datasets, together with new and better analysis tools, will increase the efficiency of agency review and evaluation of nonclinical data.

CDER recently completed a related pilot project (phase 1) that asked for volunteers from industry to submit sample nonclinical datasets in the SEND format outside of a regulatory setting (68 FR 3885; January 27, 2003). The phase 1 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 efficiently display and evaluate data from animal toxicity studies submitted in the SEND format. The phase 1 pilot resulted in development of a SEND Implementation Guide (Version 2.3; November 2005), which is available on the CDISC Web site (*http://www.cdisc.org/models/send/v2.3/SENDV2.3ImplementationGuide.pdf*). The SEND Implementation Guide describes the process for formatting nonclinical data from single- and repeat-dose animal toxicity and carcinogenicity studies for submission purposes. The pilot also resulted in the development of specialized software tools for validating, displaying, and analyzing SEND-formatted nonclinical data.

As a continuation of this testing process, this new pilot (phase 2) will enable FDA to evaluate 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.

In addition, in the intervening time period between the publication of the SEND implementation guide version 2.3 (November 2005) and now, some changes have been made to the SDTM for clinical data, making it desirable to update the SEND implementation guide to ensure harmonized implementation of the CDISC study data standard across both clinical and nonclinical data. There is also a plan to expand the SEND implementation guide to include a pharmacokinetics domain, more detailed implementation examples, and, eventually, other nonclinical study types. As a result, FDA will not conduct the pilot using the existing SEND implementation guide version 2.3. Instead, phase 2 will include an initial collaboration among FDA, available pilot participants, and the SEND Consortium to update and create a new draft SEND implementation guide before FDA receives any datasets for regulatory review. The current status of