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 [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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:

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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.

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