

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 02N-0532]

Nonclinical Datasets; Notice of Pilot Project

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is seeking volunteers to participate in a pilot project involving the evaluation of various analysis tools to facilitate the use of electronic datasets for analysis of animal data submitted to FDA by applicants of new drug applications (NDAs). These analysis tools will allow a reviewer to more efficiently display and evaluate nonclinical datasets submitted in electronic format.

**DATES:** Submit written requests to participate in the pilot project by [*insert date 60 days after date of publication in the Federal Register*]. Comments on this pilot project may be submitted at any time.

**ADDRESSES:** Submit written requests to participate and comments regarding the pilot project to the Dockets Management Branch (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:** Randy Levin, Center for Drug Evaluation and Research (HFD-001), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5411, [levinr@cderr.fda.gov](mailto:levinr@cderr.fda.gov).

**SUPPLEMENTARY INFORMATION:**

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Certifier [Signature]

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## I. Background

Under current FDA regulations (21 CFR 314.50), applicants must provide nonclinical data in NDAs. In January 1999, the agency published guidance describing how applicants could provide nonclinical data in the form of electronic datasets. In the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—NDAs,” FDA provided recommendations on how to organize the datasets and how to provide descriptive information on the datasets and the data variables (metadata). The Center for Biologics Evaluation and Research (CBER) has provided similar recommendations for biologics license applications (BLAs) in their guidance entitled “Providing Regulatory Submissions in Electronic Format—BLAs.” A joint CBER and CDER guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—General Considerations,” which published in January 1999, provided recommendations for the file formats for nonclinical datasets.

Recently, FDA received recommendations for a standard presentation of certain clinical data from the Clinical Data Interchange Standards Consortium, Inc. (CDISC), a nonprofit organization including members from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors. CDISC is currently facilitating the work on similar standards for nonclinical datasets. Where possible, the standards developed for clinical datasets and metadata should be used in the development of standardized presentations of the datasets for routine toxicology studies (e.g., chronic toxicology and carcinogenicity studies).

In addition, CDER has entered into a cooperative research and development agreement with PharmQuest Corp. for the development of analysis tools by which to evaluate the nonclinical datasets prepared using

defined standards. The use of these standardized datasets will reduce the amount of effort required of the reviewer to evaluate nonclinical data.

The purpose of the pilot project is to help in the development of analysis tools designed to facilitate the review and evaluation of electronic nonclinical datasets and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized nonclinical data and metadata.

## **II. Pilot Project Description**

This pilot project is part of an effort to improve the process for submitting nonclinical data. Eventually, FDA expects to recommend detailed data standards for the submission of nonclinical data. Participants in this pilot project will have the opportunity not only to assist the agency in testing the use of various analysis tools and standardized nonclinical data and metadata, but would also be able to familiarize themselves with the process at an early stage of development. Only a few participants are needed for this pilot.

### *A. Initial Approach*

Because a limited group of voluntary participants are needed, the agency will use its discretion in choosing volunteers, based on their having previously submitted nonclinical datasets to FDA and having demonstrated familiarity with our recommendations for creating nonclinical datasets as presented in the guidance for industry entitled “Providing Regulatory Submissions in Electronic Format—NDAs.” During the pilot project, specific technical instructions for providing the nonclinical data for testing will be made available to pilot participants. Participants in the pilot project will be asked to provide nonclinical datasets as described in the technical instructions and to provide technical feedback.

### *B. Scope*

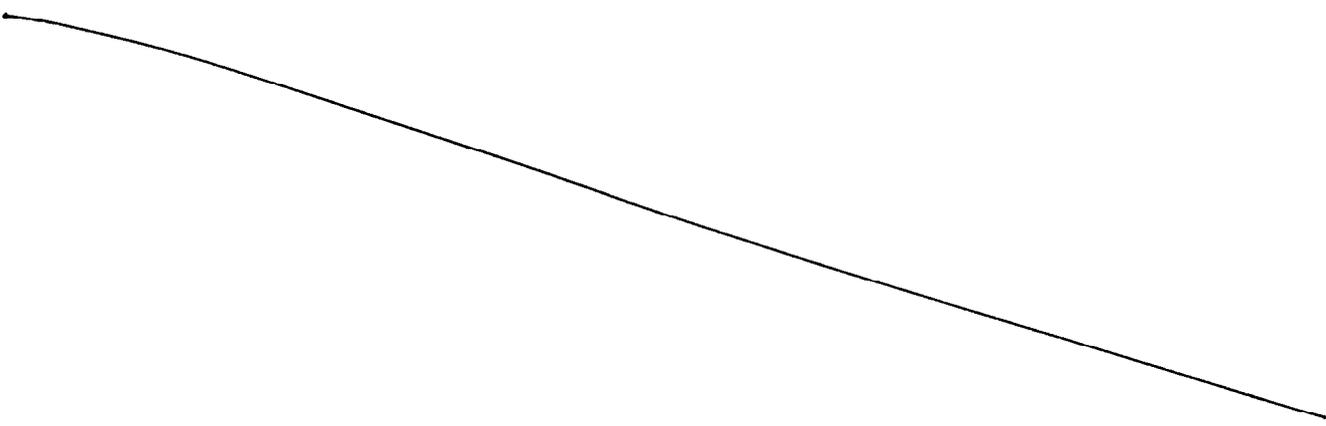
Existing requirements for the submission of nonclinical data will not be waived, suspended, or modified for purposes of this pilot project. The pilot project will test the preparation and use of the submitted nonclinical electronic datasets.

### *C. How to Participate*

Written requests to volunteer should be submitted to the Dockets Management Branch (see **ADDRESSES**). Requests are to be identified with the docket number found in brackets in the heading of this document.

## **III. Comments**

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written or electronic comments regarding this pilot project. Submit a single copy of electronic comments to <http://www.fda.gov/dockets/ecomments> or two hard copies of any written comments, except that individuals may submit one hard copy. Comments are to be identified with the docket number found in brackets in the heading of this document. We will consider all received comments in making a determination on electronic filing and when drafting a guidance document for submitting nonclinical study data



as electronic datasets. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 1, 15, 2003  
January 15, 2003.

  
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Margaret M. Dotzel,  
Assistant Commissioner for Policy.

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