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SUPPLEMENTARY INFORMATION:

I. Background

Under current FDA regulations (21 CFR 314.50), applicants must provide CRTs with NDAs. Since November 1997, under 21 CFR part 11, we have accepted CRTs in electronic format instead of paper.

We have published several guidance documents that provide recommendations concerning electronic submissions. In the **Federal Register** of January 28, 1999 (64 FR 4432), CDER published the guidance entitled "Providing Regulatory Submissions in Electronic Format—NDAs." This guidance describes how applicants can provide CRTs as electronic datasets. This guidance also offers recommendations on how to organize the datasets and how to provide descriptive information on the datasets and the data variables (metadata). In the **Federal Register** of November 12, 1999 (64 FR 61647), the Center for Biologics Evaluation and Research (CBER) provides similar recommendations for biologic 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," provides recommendations for the file formats for clinical datasets (64 FR 4433, January 28, 1999).

The datasets described in these guidance documents are organized by domain (e.g., labs, adverse events). For NDAs, however, we also recommend the submission of CRTs organized by individual patients—a format we call patient profiles. Patient profiles are provided in portable document format (PDF) and not as electronic datasets. Patient profiles are not recommended for submissions to CBER. CDER is working with CBER to update the guidance documents with more detailed standards for the submission of CRT datasets and metadata.

Recently, we have received recommendations for a standard presentation of the most common CRT datasets and metadata from the Clinical Data Interchange Standards Consortium, Inc. (CDISC). CDISC is a nonprofit organization and its members are from pharmaceutical companies, biotechnology companies, contract research organizations, and software vendors.

CDER has also entered into a CRADA with PPD Informatics (PPD) to develop a module for PPD's commercially available CrossGraphs software that will generate patient profiles directly from CRT datasets provided with NDA submissions. The use of standardized datasets and metadata reduces the amount of preparation required by the reviewer to generate patient profiles and would eliminate the need for applicants to provide patient profiles in PDF. The purpose of the pilot project is to test the PPV module with standardized datasets and metadata and to obtain feedback from reviewers and pharmaceutical companies on the creation and use of standardized clinical data and metadata.

II. Pilot Project Description

The pilot project is part of an effort to improve the standards for submission of clinical data. Eventually, we expect to recommend detailed clinical data and metadata standards for the submission of CRTs. Participants in this PPV pilot project will not only assist us in testing the use of the PPV and standard clinical data and metadata but will also 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 number of voluntary participants are needed, the agency will use its discretion in choosing volunteers, based on their experience with providing CRTs and their familiarity with the standards recommended by CDISC. During the pilot project, the agency will make available to the public specific technical instructions for providing the clinical data and metadata for testing. See the **Electronic Access** section for instructions. Participants in the pilot

project will be asked to provide clinical trial datasets and metadata as described in the technical instructions and to provide technical feedback.

B. Scope

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

III. Pilot Project Participation

Written requests to volunteer for the pilot project should be submitted to the Dockets Management Branch (address above). Requests are to be identified with the docket number found in brackets in the heading of this document.

IV. Comments

Interested persons may submit to the Dockets Management Branch (mail and electronic addresses above) written comments regarding this pilot project. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider comments in making a determination on electronic filing and in drafting a guidance document for submitting clinical trial data and metadata electronically. Received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

These instructions will be available on the Internet at <http://www.fda.gov/cder/regulatory/ersr/default.htm>.

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Margaret M. Dotzel,
Associate Commissioner for Policy.

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