federal government agencies such as NIH and FDA, state and local governments, medical schools, schools of public health, colleges and universities, private businesses, nonprofit foundations and corporations, professional associations, as well as individual practitioners, researchers, administrators and health planners. Uses vary from the inclusion of a few selected statistics in a large research effort, to an in-depth analysis of the entire NAMCS data set covering several years.

To calculate the burden hours the number of respondents for NAMCS is based on a sample of 3,150 physicians with a 50 percent participation rate (this includes physicians who are out-of-scope as well as those who refuse). The total cost to respondents is estimated to be $300,000.

Respondents	Number of respondents	Number of response/respondent	Avg. burden/responses (in hrs.)	Response burden (in hrs.)
Office-based physicians Induction form	1,575	1	25/60	656
Patient record form	1,575	30	5/60	3,938
Total				4,594

Dated: November 30, 2001.

Nancy E. Cheal,

Acting Associate Director for Policy, Planning and Evaluation, Centers for Disease Control and Prevention.

[FR Doc. 01–30397 Filed 12–7–01; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01N–0496]

Patient Profile Viewer; 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 testing of the Patient Profile Viewer (PPV). The PPV is computer software that allows a reviewer to display data collected from case report tabulations (CRTs) submitted in electronic format. We are working with PPD Informatics to develop the PPV under a Cooperative Research and Development Agreement (CRADA) in an effort to improve review efficiency, develop standards for submission of data, and eliminate the need for the submission of patient profiles by applicants of new drug applications (NDAs). To help in this development, we are seeking volunteers to provide CRT datasets from clinical studies to test the PPV. Data supplied during the pilot project will not replace any regulatory requirements for submitting CRTs.

DATES: Submit written or electronic requests to participate in the pilot project by January 9, 2002. Comments on the pilot project may be submitted at any time.

ADDRESSES: Submit written requests to participate and comments regarding this pilot project to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written comments on the pilot project to the Dockets Management Branch (address above). 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, e-mail: levinr@cder.fda.gov.

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.

Dated: December 3, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–30430 Filed 12–5–01; 11:21 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0532]

Food Code; 2001 Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 2001 revision of the Food Code (2001 Food Code). This 2001 revision was initiated in cooperation with the Conference for Food Protection (CFP or Conference) to help ensure that food sold or offered for human consumption by retail food establishments is safe, unadulterated, and honestly presented.

DATES: Submit written or electronic comments on the 2001 Food Code at any time.

ADDRESSES: Submit written requests for single copies of the 2001 Food Code to the Office of Field Programs (HFS–600), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 200 C St. SW., Washington, DC 20204 (after December 14, 2001, the Center for Food Safety and Applied Nutrition's address will be 5100 Paint Branch Pkwy., College Park, MD 20740). Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on the 2001 Food Code 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. See the **SUPPLEMENTARY INFORMATION** section for electronic access and ordering information for the 2001 Food Code.

FOR FURTHER INFORMATION CONTACT: Glenda R. Lewis, Center for Food Safety and Applied Nutrition (HFS–627), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–8140. (After December 14, 2001, the Center for Food Safety and Applied Nutrition's address will be 5100 Paint Branch Pkwy., College Park, MD 20740.)

SUPPLEMENTARY INFORMATION:

I. Background

FDA provides assistance to Federal, State, local, and tribal governmental bodies with jurisdiction over food safety to help ensure that food provided to consumers by retail food establishments is not a vehicle of communicable diseases. A primary mechanism for providing that assistance is the regular publication of a model code that sets out FDA's best advice for a uniform system of regulation that is designed to help ensure that food sold or offered for human consumption by retail food establishments is safe, unadulterated, and honestly presented.

In 1971, the CFP was established to provide a dialogue on food safety issues. The CFP is a voluntary organization comprised of Federal, State, and local regulatory officials, food industry representatives, consumer groups, and academia. The public also may participate in the CFP process. The Conference meets biennially for discussion among all parties regarding ways to improve food safety in the retail segment of the food industry. FDA recognizes the CFP as a voluntary national organization that is qualified to provide technical guidance and information toward the development and implementation of codes and standards pertaining to retail food service, retail food stores, and retail vending operations. At the 1986 meeting of the CFP, it was recommended that the three distinct model codes in existence at that time (retail food stores, food service facilities, and vending) be combined into a Food Protection Unicode. The CFP endorsed this approach, FDA concurred, and issued the first Food Code in 1993. FDA has issued subsequent versions of the Food Code every 2 years. Revisions to the Food Code are based in part on recommendations that are cooperatively developed by CFP members in response to issues submitted to the CFP by interested parties.

The 2001 Food Code responds to recommendations made by the CFP and addresses needed clarifications, updates, and corrections. Significant changes between the 2001 Food Code and the 1999 Food Code include the following:

- A revised definition of juice, information on juice treated to control