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

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

Margaret M. Dotzel, 
Associate Commissioner for Policy. 
[FR Doc. 01–30430 Filed 12–5–01; 11:21 am]

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 Drug Administration (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