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

pathogens, and information that addresses issues relating to juice provided to populations that are particularly vulnerable to foodborne illness;

- A revised definition of ''highly susceptible populations'' and new definitions relating to employee health including ''exclusion'' and ''restriction'';
- New provisions for the refrigeration and labeling of eggs consistent with new requirements in the Code of Federal Regulations (CFR);
- An updated roast beef cooking chart consistent with new U.S. Department of Agriculture/Food Safety and Inspection Service criteria;
- A revised preface to recognize Federal performance standards relating to food products and processes. (Federal performance standards are acceptable, equivalent alternatives to the command-and-control provisions that now provide specific times and temperatures for cooking);
- A new definition for ''shiga toxin-producing *E. coli*'' and a replacement of references to ''*E. coli 0157:H7* ''with Ashiga toxin-producing *E.* coli'';
- Clarification of hand washing procedures with respect to time and water temperature; application of hand washing procedures to persons with prosthetic devices; and hand washing procedures before donning gloves;
- Clarification of the provisions relating to marking refrigerated, ready-to-eat food to indicate its shelf life;
- A new provision that allows the use of a thermometer embedded in a nonfood substance as a means of monitoring the temperature of food products in a refrigerator, as well as encouraging the use of small diameter probes for measuring the internal temperature of thin masses of food;
- New provisions that address backflow prevention devices for beverage carbonators;
- Additional references relating to time as a public health control and cooling; and
- Provisions updated to reflect consistency with the current CFR and guidances issued by Federal agencies.

The 2001 Food Code is a level 1 guidance being issued consistent with FDA's good guidance practices regulation in § 10.115 (21 CFR 10.115). With certain exceptions, this regulation requires that the public be afforded an opportunity to comment on level 1 guidance documents before their implementation. FDA is not seeking public comment before implementing this edition of the Food Code because we have determined that it is not feasible or appropriate in accordance with § 10.115(g)(2). The Food Code is revised biennially to keep it up-to-date. Each revision is based on comments received on a previous Food Code, as well as issues presented to the CFP for further development and discussion. Each revision also reflects current public comment. The Conference engages in outreach in a number of ways. First and foremost, its members communicate within their respective constituencies (industry—retail food store, food service, vending, processing; government—Federal, State, and local; consumer and academia). In addition, the Conference has a Web site at http://www.foodprotect.org; press releases go out to various organizations; and members receive a Conference newsletter. Thus, each revision of the Food Code is part of an ongoing dialogue and serves effectively as a ''draft'' for the next revision.

The 2001 Food Code does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such an approach satisfies the requirements of applicable statutes and regulations.

II. Comments

The public may comment on this document at any time. The public may comment in one of two ways: (1) By participating in the CFP meeting held biennially for the purpose of, among other things, considering recommended changes to the Food Code; or (2) by commenting in writing or electronically to FDA. Comments submitted to the agency may be offered for consideration and vote at a subsequent CFP meeting.

Interested persons, at any time, may submit written or electronic comments to the Dockets Management Branch (address above) on the 2001 Food Code. 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. The 2001 Food Code and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access and Ordering Information

Persons with access to the Internet may obtain the document at http://www.cfsan.fda.gov/dms/guidance.html, http://vm.cfsan.fda.gov/list.html, or http://www.fedworld.com. In addition, the 2001 Food Code may be ordered from the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, 1–800–553–6847, in several formats: Docutek copy, spiral bound, Microsoft Word 97 files on diskette, enhanced electronic version on cassette or CD–ROM, including Adobe Reader. The enhanced versions include electronic features such as hypertext links that enable the reader to locate quickly a specific code provision and to read simultaneously the text of cross-referenced documents.

Dated: December 5, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 01–30489 Filed 12–5–01; 4:08 pm]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services notifies Federal agencies of the laboratories currently certified to meet standards of Subpart C of Mandatory Guidelines for Federal Workplace Drug Testing Programs (59 FR 29916, 29925). A notice listing all currently certified laboratories is published in the **Federal Register** during the first week of each month. If any laboratory's certification is suspended or revoked, the laboratory will be omitted from subsequent lists until such time as it is restored to full certification under the Guidelines.

If any laboratory has withdrawn from the National Laboratory Certification Program during the past month, it will be listed at the end, and will be omitted from the monthly listing thereafter.

This notice is also available on the internet at the following websites: *http://workplace.samhsa.gov; http://www.drugfreeworkplace.gov;* and *http://www.health.org/workplace.*

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersh or Dr. Walter Vogl, Division of Workplace Programs, 5600 Fishers Lane, Rockwall 2 Building, Room 815, Rockville, Maryland 20857; Tel.: (301) 443–6014, Fax: (301) 443–3031.

SUPPLEMENTARY INFORMATION: Mandatory Guidelines for Federal Workplace Drug Testing were developed in accordance with Executive Order 12564 and section 503 of Pub. L. 100–