TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN

Form No.	21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
FDA Form 2657 Transmittal of Labels and Circulars	601.2(a) and 601.12(a)	387	7.2	2,800	.16	448

There are no capital costs or operating and maintenance costs associated with this information collection of information.

Dated: September 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24954 Filed 9–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0378]

Food Code; 1997 Revision; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the 1997 revision of the Food Code. This 1997 revision was initiated in cooperation with the Conference for Food Protection (CFP) to help ensure that safe, unadulterated, and honestly presented food is sold or offered for human consumption by retail food establishments.

ADDRESSES: The 1997 revision of the Food Code is available for public examination in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT:

Regarding questions about this document: Betty Harden, Office of Field Programs, Center for Food Safety and Applied Nutrition (HFS–627), 200 C St. SW., Washington, DC 20204, 202–205–8140.

Regarding additional information about the CFP: Leon Townsend, Conference for Food Protection, 110 Tecumseh Trail, Frankfort, KY 40601, 502–695–0253.

SUPPLEMENTARY INFORMATION: FDA provides assistance to local, State, and Federal governmental bodies to ensure that the food that is provided to consumers by retail food establishments is not a vector of communicable diseases. One mechanism for providing that assistance is the publication of a model code that sets out FDA's best advice for a uniform system of regulation to ensure that the food sold or offered for human consumption at retail is safe, properly protected, and accurately presented.

The CFP was originally established in 1971 by State and Federal officials and by representatives of industry. In 1988, the CFP adopted a constitution and by-laws to provide a formal structure under which State regulatory authorities could meet and consider guidelines for improving food safety in the retail segment of the food industry.

At the 1986 CFP meeting, FDA presented a White Paper that recommended combining the three distinct model codes that existed at that time (retail food stores, food service facilities, and vending) into a Food Protection Unicode. The CFP endorsed the approach that FDA would develop a model Food Protection Unicode as a priority project. FDA formed a Unicode Task Group and published a notice of the Unicode's availability for comment in the **Federal Register** of May 9, 1988 (53 FR 16472), when the Task Group completed a draft. Based on comments submitted in response to that notice, and in consideration of subsequent comments provided by regulatory officials, industry representatives, academia, and consumer representatives at the CFP meetings in 1988, 1990, and 1992, FDA modified the document and finalized it as the 1993 Food Code. Based on field application trials, further comment, and input from the 1994 CFP meeting, FDA issued a revised version of the 1993 Food Code as the 1995 Food Code.

The CFP wrote a letter to FDA on May 28, 1996, and suggested changes in the 1995 Food Code. The CFP developed these suggestions in cooperation with the Association of Food and Drug Officials (AFDO).

The 1997 Food Code responds to those suggestions. Noteworthy changes from the 1995 Food Code include the following:

(1) Modification of the definition of potentially hazardous food to specifically state that a food might contain pathogens even though it does not qualify as a potentially hazardous food;

(2) Identification of three methods of complying with the knowledge requirements for the person in charge;

(3) Addition of *Shigella* spp. and *E. coli* O157:H7 to the list of organisms that warrant restriction or exclusion if a food worker is found to be an asymptomatic shedder;

(4) Removal of the special handwashing procedures and reservation of that section;

(5) Allowance for the storage of potentially hazardous food at 45 °F (7 °C) under certain conditions;

(6) Adjustment of the number of days that prepared foods may be stored at 41 °F (5 °C) and 45 °F from 10 to 7 and from 3 to 4, respectively;

(7) Revision of certain cooking temperatures and times, e.g., for preparing ratites and formed roast beef and for microwave cooking;

(8) Modifications throughout the document to coincide with the seafood hazard analysis critical control point rule at 21 CFR parts 123 and 1240;

(9) Provision for the regulatory authority to approve alternatives to the rule of no bare hand contact with ready-to-eat food;

(10) Insertion of an explanation of the current status of the consumer advisory language recommended by the CFP;

(11) Use of the term ''raw shell eggs'' to distinguish provisions that apply to in-shell eggs versus in-shell eggs that were subjected to in-shell pasteurization at a food processing plant;

(12) Addition of a statement that shell eggs placed, upon receipt, in a refrigerated unit that maintains food at the required temperature constitutes satisfactory compliance;

(13) Addition of a section that collates and expands the Food Code's special precautions for highly susceptible populations;

(14) Removal of the requirement for a specified carbonator backflow prevention device and reservation of the section; and

(15) Update of information and addition of user aides in the annexes.

The 1997 revision of the Food Code is available for public examination in

the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Copies of the 1997 Food Code are available on the World Wide Web at http://vm.cfsan.fda.gov/list.html or at http://www.fedworld.com. The 1997 Food Code also may be purchased from the National Technical Information Service, U.S. Department of Commerce, Springfield, VA 22161, in several formats: Spiral bound, WordPerfect 6.1 files on diskette, or enhanced electronic version on diskette or CD–Rom. The enhanced versions include electronic features such as hypertext links that enable the reader to quickly locate a specific code provision and to simultaneously read the text of cross-referenced documents.

Dated: September 12, 1997.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 97–24956 Filed 9–18–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0362]

A New 510(k) Paradigm; Draft of Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications.'' The draft 510(k) paradigm, which is neither final nor in effect at this time, presents two alternative methods of demonstrating substantial equivalence in premarket notifications, and it is intended to conserve FDA's review resources while facilitating the introduction of safe and effective devices into interstate commerce. The paradigm addresses the type of data needed by the Center for Devices and Radiological Health (CDRH) to implement alternative procedures in establishing substantial equivalence. The agency requests comments on this draft paradigm.

DATES: Submit written comments by November 18, 1997.

ADDRESSES: Submit written requests for single copies of the draft paradigm entitled ''A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the paradigm. Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20850.

FOR FURTHER INFORMATION CONTACT: Robert I. Chissler, Program Operations Staff (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–1190.

SUPPLEMENTARY INFORMATION:

I. Background

The draft paradigm announced in this document presents device manufacturers with several optional approaches for obtaining marketing clearance for their Class II devices. While the draft paradigm maintains the traditional method of demonstrating substantial equivalence under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360(k)), it also represents two alternatives. The first alternative, the ''Special 510(k): Device Modification,''utilizes certain aspects of the quality system regulation, while the second alternative, the ''abbreviated 510(k),'' relies on the use of special controls and consensus standards to facilitate 510(k) review.

Under section 510(k) of the act, a person who intends to introduce a device into commercial distribution is required to submit a premarket notification, or 510(k), to FDA at least 90 days before commercial distribution is to begin. Section 513(i) of the act (21 U.S.C. 360c(i)) stipulates that FDA may issue an order of substantial equivalence, only upon making a determination that the device to be introduced into commercial distribution is as safe and effective as a legally marketed device. Under 21 CFR 807.87, FDA has codified the content requirements for premarket notifications to be submitted by device manufacturers in support of the substantial equivalence decision. However, FDA has discretion in the type of information it deems necessary to meet those content requirements.

A. Special 510(k): Device Modification

The Safe Medical Devices Act of 1990 (the SMDA) (Pub. L. 101–629) amended section 520(f) of the act (21 U.S.C. 360j(f)), providing FDA with the authority to issue regulations requiring pre-production design controls. Under the authority provided by the SMDA, FDA revised its current good manufacturing practice requirements to include pre-production design controls that device manufacturers must follow when initially designing devices or when making subsequent modifications to those designs.

Effective June 1, 1997, manufacturers of Class II and certain Class I devices must follow design control procedures for their devices including device modifications. Product modifications that could significantly affect safety and effectiveness are subject to 510(k) submission requirements under 21 CFR 807 as well as design control requirements under 21 CFR 820.30.

Because design controls are now in effect and require the conduct of verification and validation studies of a type that have traditionally been included in 510(k) submissions, FDA believes that test results generated under the new design control requirements will be sufficient to serve as a basis for certain substantial equivalence decisions. In light of the design control requirements, FDA believes that it may be appropriate, in certain circumstances, to forgo a detailed review of the underlying data normally required in 510(k)'s. While FDA would not rely on the design controls procedure requirements to issue a determination of substantive equivalence, it would rely on the existence of data generated in accordance with those procedures to issue a substantial equivalence determination.

Under the draft 510(k) paradigm, a manufacturer would use the FDA guidance document entitled, ''Deciding When to Submit A 510(k) for a Change to an Existing Device'' to decide if a device modification could be implemented without submission of a new 510(k). If a new 510(k) is needed for the modification and if the modification does not affect the intended use of the device or the basic fundamental scientific technology of the device, conformance with design controls could form the basis for clearing the application.

Special 510(k)'s will be processed by the Office of Device Evaluation (ODE) within 30 days of receipt by the