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]

BILLING CODE 4160–01–F

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

Document Mail Center (DMC). Modifications which affect the intended use or alter the basic fundamental scientific technology of the device are not appropriate for review under this type of application, but rather they should continue to be subject to routine 510(k) procedures or may be subject to an ''Abbreviated 510(k)'' as described in section I.B of this document.

B. Abbreviated 510(k)

The SMDA introduced the concept of special controls as the means by which the safety and effectiveness of Class II devices can be ensured. Special controls are defined by statute as those controls that provide reasonable assurance of the device's safety and effectiveness. Recently, considerable effort has been expended to develop the concept of a ''special control guidance document'' (SCGD). Under this initiative, reasonably foreseeable risks that are associated with a type of Class II device would be identified in a SCGD. For each risk, the agency would also identify a special control(s) such as a consensus standard, labeling content, or postmarket surveillance that would address the risk.

In addition to SCGD's that would be developed for generic Class II devices, CDRH is committed to recognizing individual consensus standards. The consensus standards could be cited in SCGD's, recognized in individual policy statements, or identified as ''special controls'' that address specific risks associated with multiple device types. IEC 60601 is an example of such a consensus standard. It has broad applicability to many electromedical devices. FDA's recognition of this standard, combined with modified review procedures, could streamline the review of many 510(k)'s for devices covered by the standard. Finally, by using the accompanying particular standards to adapt the general standard to specific devices, the 510(k) review process may be further expedited.

Under the draft paradigm, device manufacturers could choose to submit ''Abbreviated 510(k)'s'' for Class II devices when a SCGD exists or when FDA has recognized an individual special control such as a relevant standard. The incentive for manufacturers to elect to use special controls or to declare conformance to recognized standards would be a more expedient review of their submissions.

II. Electronic Access

In order to receive ''A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications'' document via your fax machine, call the CDRH Facts-On-Demand (FOD) system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number (905) followed by the pound sign (#). Then follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the paradigm may also do so by using the World Wide Web (WWW). CDRH maintains an entry on the WWW for easy access to information including text, graphics, and files that may be downloaded to a personal computer with access to the Web. The CDRH home page, which is updated on a regular basis, includes: The draft document entitled ''A New 510(k) Paradigm—Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications,'' device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh. The paradigm will be available at http://www.fda.gov/cdrh/ode/parad510.html.

A text-only version of the CDRH Web site is also available from a computer or VT–100 compatible terminal by dialing 800–222–0185 (terminal settings are 8/1/N). Once the modem answers, press Enter several times and then select menu choice 1: FDA BULLETIN BOARD SERVICE. From there follow instructions for logging in, and at the BBS TOPICS PAGE, arrow down to the FDA home page (do not select the first CDRH entry). Then select Medical Devices and Radiological Health. From there select CENTER FOR DEVICES AND RADIOLOGICAL HEALTH for general information, or arrow down for specific topics.

III. Comments

Interested persons may, submit to the Dockets Management Branch (address above) written comments regarding this paradigm by November 18, 1997. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments and requests for copies are to be identified with the docket number found in brackets in the heading of this document. The paradigm and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 1997.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 97–24955 Filed 9–18–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel meeting:

Name of SEP: HLA Genotyping.
Date: October 8, 1997.
Time: 3:00 p.m.
Contact Person: William Elzinga, Ph.D., Scientific Review Administrator, Review Branch, NIDDK, Natcher Building, Room 6as–37A, National Institutes of Health, Bethesda, Maryland 20892–6600, Phone: (301) 594–8895.
Purpose/Agenda: To review and evaluate grant applications.

This meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5 U.S.C. Applications and/or proposals and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications and/or proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program No. 93.847–849, Diabetes, Endocrine and Metabolic Diseases; Digestive Diseases and Nutrition; and Kidney Diseases, Urology and Hematology Research, National Institutes of Health)

Dated: September 12, 1997.

LaVerne Y. Stringfield,

Committee Management Officer, NIH.

[FR Doc. 97–24884 Filed 9–18–97; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Division of Research Grants; Notice of Closed Meetings

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following