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