classification framework presumes that the risk presented by a particular device depends on its intended purpose and the effectiveness of the risk management techniques applied during the design, manufacture, and use of that device. The document also suggests that the regulatory controls applied should be proportional to the level of risk associated with a medical device and should increase with the associated degree of risk presented by the medical device. The GHTF document suggests four global classifications of devices.

This document also presents a decision tree logic that may help regulatory authorities develop different parameters that might be used to classify specific devices.

When FDA discusses draft documents with representatives of other countries, we seek public comment on the resulting documents. We believe that it is important to publish draft documents for comment at the same time as other countries so we may review the public comments and resume discussions in a timely manner. Because other countries do not follow our good guidance practices (GGPs), we do not require draft documents that result from international discussions to comply with the format requirements of our GGP regulation. The GGP regulation does require that any final FDA guidance that results from international discussions will comply with the GGP regulation.

II. Electronic Access

In order to receive ''Medical Devices Classification'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number (1327) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft document may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, 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.

III. Comments

Interested persons may, at any time, submit to the Dockets Management Branch (address above) written comments regarding this draft guidance. FDA must submit its written comments to the GHTF by July 1, 2001. FDA will consider any comments that it receives in a timely manner, while preparing those comments. FDA will consider any public comments that it receives after preparation of its comments to GHTF in future discussions on this issue. Submit two copies of any comments, 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 guidance document and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: May 7, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

[FR Doc. 01–12226 Filed 5–15–01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–10041]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Type of Information Collection Request: New collection; *Title of Information Collection:* Long Term Care Awareness Project; *Form No.:* HCFA–10041 (OMB# 0938–NEW); *Use:* HCFA needs to collect data to pilot test a national campaign to educate current and future Medicare beneficiaries and their families about long term health care needs, as requested in the Clinton Fiscal Year 2000 Budget, to design and implement a nationwide campaign. Respondents will be from two groups: 55–70 year-olds and 18–64 years old persons with disability; *Frequency:* Quarterly; *Affected Public:* Individuals or households; *Number of Respondents:* 7,800; *Total Annual Responses:* 3,900; *Total Annual Hours:* 800.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at *http://www.hcfa.gov/regs/prdact95.htm,* or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the HCFA Paperwork Clearance Officer designated at the following address: HCFA, Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards, Attention: Julie Brown, Attn. 10041, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: May 8, 2001.

Julie Brown,

Acting Reports Clearance Officer, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 01–12342 Filed 5–15–01; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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 meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C.,