

that such radiation doses may have endangered the health of members of this class. The Subcommittee for Dose Reconstruction Reviews was established to aid the Advisory Board in carrying out its duty to advise the Secretary, HHS, on dose reconstruction.

*Matters to be Discussed:* The agenda for the Subcommittee meeting includes: a discussion of cases under review from the 6th, 7th, and 8th sets of individual dose reconstructions; preparation of a letter report on the first 100 dose reconstruction cases reviewed; and, an update on site-specific dose reconstruction guidelines.

The agenda is subject to change as priorities dictate.

In the event an individual cannot attend, written comments may be submitted. Any written comments received will be provided at the meeting and should be submitted to the contact person below well in advance of the meeting.

*Contact Person for More Information:* Theodore Katz, Executive Secretary, NIOSH, CDC, 1600 Clifton Road, Mailstop E-20, Atlanta, GA 30333, Telephone (513) 533-6800, Toll Free 1(800) CDC-INFO, e-mail [ocas@cdc.gov](mailto:ocas@cdc.gov).

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: November 13, 2008.

**Elaine L. Baker,**

*Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. E8-27447 Filed 11-18-08; 8:45 am]

**BILLING CODE 4163-18-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Administration for Children and Families**

**Proposed Information Collection Activity; Comment Request**

*Proposed Projects:*

**ANNUAL BURDEN ESTIMATES**

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Letter of Intent .....	562	1	1	562

*Estimated Total Annual Burden Hours:* 562.

In compliance with the requirements of section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. *E-mail address:* [infocollection@acf.hhs.gov](mailto:infocollection@acf.hhs.gov). All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the

collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Dated: November 13, 2008.

**Janean Chambers,**

*Reports Clearance Officer.*

[FR Doc. E8-27358 Filed 11-18-08; 8:45 am]

**BILLING CODE 4184-01-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA-2008-N-0526]

**Global Harmonization Task Force, Study Group 1; Proposed and Final Documents; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of proposed and final documents that have been prepared by Study Group 1 of the Global

*Title:* Letter of Intent for Indian Tribes, Tribal organizations or Tribal consortia to operate a title IV-E program under the Fostering Connections to Success and Increasing Adoptions Act of 2008 (Pub. L. 110-351).

*OMB No.:* New Collection.

*Description:* The Administration for Children and Families is requesting that Indian tribes, tribal organizations or tribal consortia that wish to apply for direct title IV-E funding pursuant to section 479B of the Social Security Act send a letter expressing their intent to facilitate budget and staff planning.

*Respondents:* Indian Tribes, Tribal organizations and Tribal consortia.

Harmonization Task Force (GHTF). These documents represent a harmonized proposal and recommendation from the GHTF Study Group that may be used by governments developing and updating their regulatory requirements for medical devices. These documents are intended to provide information only and do not describe FDA's current regulatory requirements; elements of these documents may not be consistent with current U.S. regulatory requirements. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

**DATES:** Submit written or electronic comments on these documents by February 17, 2009. After February 17, 2009, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

**ADDRESSES:** Submit written requests for single copies of these documents to the Division of Small Manufacturers, International, and Consumer Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug

Administration, 1350 Piccard Dr., Rockville, MD 20850. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 240-276-3151. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the documents.

Submit written comments concerning these documents to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:**

Ginette Y. Michaud, Center for Devices and Radiological Health (HFZ-480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 240-276-3700.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

FDA has participated in a number of activities to promote the international harmonization of regulatory requirements. In September 1992, a meeting was held in Nice, France by senior regulatory officials to evaluate international harmonization. This meeting led to the development of the organization now known as GHTF to facilitate harmonization. Subsequent meetings have been held in various locations throughout the world.

The GHTF is a voluntary group of representatives from national medical device regulatory authorities and the regulated industry. Since its inception, the GHTF has been comprised of representatives from five founding members grouped into three geographical areas: Europe, Asia-Pacific, and North America, each of which actively regulates medical devices using its own unique regulatory framework.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices to facilitate trade while preserving the right of participating members to address the protection of public health by regulatory means considered most suitable. One of the ways this objective is achieved is by identifying and developing areas of international cooperation to facilitate progressive reduction of technical and regulatory differences in systems established to regulate medical devices. In an effort to accomplish these objectives, the GHTF formed five study groups to draft documents and carry on other activities designed to facilitate

global harmonization. This notice relates to documents that have been developed by one of the Study Groups (Study Group 1).

Study Group 1 was initially tasked with the responsibility of identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidelines that could help lead to harmonization. As a result of its efforts, this group has developed SG1(PD)/N055R6:2008 and SG1/N045:2008.

The proposed document SG1(PD)/N055R6:2008 entitled "Definitions of the Terms Manufacturer, Authorized Representative, Distributor and Importer" provides a harmonized definition of the terms "manufacturer," "authorized representative," "distributor," and "importer".

The final document SG1/N045:2008 entitled "Principles of In Vitro Diagnostic (IVD) Medical Devices Classification" assists a manufacturer in allocating an IVD medical device to the appropriate risk class by using a set of harmonized classification principles. It bases such classification principles on an IVD medical device's intended use and allows regulatory authorities to rule upon matters of interpretation for a particular IVD medical device, when appropriate.

**II. Significance of Guidance**

These documents represent recommendations from the GHTF study group and do not describe regulatory requirements. FDA is making these documents available so that industry and other members of the public may express their views and opinions. In particular, FDA seeks comments on the advantages and disadvantages of the approaches in the GHTF documents, particularly where they are not consistent with current practices for the manufacture of products in the United States.

**III. Electronic Access**

Persons interested in obtaining a copy of these documents may do so by using the Internet. The Center for Devices and Radiological Health (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 device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturer's assistance, information

on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. Information on the GHTF may be accessed at <http://www.ghtf.org>. The CDRH Web site may be accessed at <http://www.fda.gov/cdrh>.

**IV. Comments**

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**), written or electronic comments regarding these documents. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

Dated: October 22, 2008.

**Daniel G. Schultz,**

*Director, Center for Devices and Radiological Health.*

[FR Doc. E8-27466 Filed 11-18-08; 8:45 am]

**BILLING CODE 4160-01-S**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**National Institutes of Health**

**Center for Scientific Review; 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 meetings.

The meetings 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., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.