

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

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Certifier N. Hawkins

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 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 *[insert date 90 days after date of publication in the Federal Register]*. After *[insert date 90 days after date of publication in the Federal Register]*, written comments or electronic comments may be submitted at any time to the contact persons listed in this document.

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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, Authorised Representative, Distributor and Importer” provides a harmonized definition of the terms “manufacturer,” “authorised 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.gh tf.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: OCT 22 2008
October 22, 2008



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