NOW THEREFORE, the parties hereto mutually agree to the terms and conditions set forth above.

FDA:

8/3/98
(Signature and date)
Lireka P. Joseph, Dr.P.H.
Director
Office of Health and Industry Programs
Center for Devices and Radiological Health
Food and Drug Administration

State of Illinois:

8/3/98
(Signature and date)
Thomas W. Ortciger
Director
Department of Nuclear Safety
State of Illinois

Dated: August 2, 1999.

William K. Hubbard,

Senior Associate Commissioner for Policy, Planning and Legislation.

[FR Doc. 99–20358 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–C

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99N–2359]

Medical Devices; Global Harmonization Task Force: Summary Technical File Documents for Premarket Documentation of Conformity With Requirements for Medical Devices; Recommendations on the Role of Standards in the Assessment of Medical Devices; and a Recommendation on Medical Device Classification; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of three documents entitled ''Summary Technical File for Premarket Documentation of Conformity With Requirements for Medical Devices;'' ''Recommendation: Role of Standards in the Assessment of Medical Devices;'' and ''Recommendation on Medical Devices Classification.'' Study group 1 of the Global Harmonization Task Force (GHTF) has prepared these documents on premarket regulation of medical devices. These documents are intended to provide information only and represent harmonized proposals and recommendations that may be used by governments developing or updating their premarket regulation schemes for medical devices. Elements of the approach set forth in these documents may not be consistent with current U. S. regulatory requirements. FDA is requesting comments on these documents.

DATES: Written comments by September 30, 1999. After the close of the comment period, written comments may be submitted at any time to Kimber C. Richter (address below).

ADDRESSES: Submit written comments on the documents to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Comments should be identified with the docket number found in brackets in the heading of this document. If you do not have access to the World Wide Web (WWW), submit written requests for single copies on a 3.5″ diskette of the document listed above 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 requests, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to these documents.

FOR FURTHER INFORMATION CONTACT: Kimber C. Richter, Office of Device Evaluation (HFZ–400), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

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. At this time it was decided to form GHTF to facilitate harmonization. Subsequent meetings have been held on a yearly basis in various locations throughout the world. The most recent GHTF meeting was held in June and July 1999, in Bethesda, MD, in the United States.

The objective of the GHTF is to encourage convergence at the global level of regulatory systems of medical devices in order 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 in order 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 has formed four study groups to draft documents and carry on other activities designed to facilitate global harmonization. This notice is a result of documents that have been developed by study group 1.

Study group 1 was formed in January 1993, and was originally tasked with identifying differences between various regulatory systems. In 1995, the group was asked to propose areas of potential harmonization for premarket device regulations and possible guidance that could help lead to harmonization. As a result of their efforts, this group has developed three draft documents that are described briefly in the following paragraphs.

(1) ''Summary Technical File for Premarket Documentation of Conformity With Requirements for Medical Devices'' (GHTF.SG1.NO11R7). Study group 1 suggests that this document should be used with the document

entitled ''Essential Principles of Safety and Performance of Medical Devices on a Global Basis; Final Working Draft'' (63 FR 46227, August 31,1998).

This document has been developed to encourage global convergence of regulatory systems and provide one means of potential future achievement. It is intended for use by medical device regulators, conformity assessment bodies, and industry, and offers an economic and effective approach to the control of medical devices in the interest of public health. The document will be of value to countries developing or amending regulations. The regulatory requirements of some countries may not, at present, reflect the contents of this document.

The purpose of this document is to propose a format and harmonized content for a summary technical file to be held by the sponsor or submitted, as required by the regulatory authority, for premarket clearance/approval. It proposes a format that may be used as an alternative to country-specific current submission formats by GHTF member states. This document summarizes the technical information needed to demonstrate conformity to premarket requirements that are consistent across various regulatory systems. Users of this document may submit it to various regulatory authorities with country specific additions as needed. (These will be defined in a second volume still under development.) Study group 1 may focus on these differences for future harmonization efforts. It should be noted that the amount of detail and information that will be needed in the summary technical file may vary considerably with the risk class of the product concerned.

(2)''Recommendation: Role of Standards in the Assessment of Medical Devices'' (GHTF.SG1.NO12R7). This GHTF document provides harmonized guidance for regulatory authorities on the use of standards in premarket regulation of devices. It suggests that international standards may assure the safety, quality and performance of medical devices and should serve as the building blocks for a harmonized regulatory process. Additionally, it recommends that regulatory authorities and industry should encourage and support the development of international standards for medical devices to demonstrate compliance with the essential principles of safety and performance of medical devices. It suggests that the use of standards is voluntary, except in those particular cases where the regulatory authority has deemed certain standards mandatory.

(3)''Recommendation on Medical Devices Classification.'' This GHTF document suggests some general guidelines for classification of medical devices to achieve eventual harmonization. It recommends that there is a need to classify medical devices based on their risk to patients, users and other persons; and that there is a benefit for manufacturers and regulatory authorities if a globally harmonized classification system is developed. This document goes on to say that there is a risk presented by a particular device and that the risk 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 Study Group 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.

These documents are presented for review and comment so that industry and other members of the public may express their views and opinions on these matters.

II. Electronic Access

Persons interested in obtaining copies of these draft documents may also do so using the WWW. Updated on a regular basis, the CDRH home page includes the document entitled ''Essential Principles for Safety and Performance of Medical Devices on a Global Basis; Final Working Draft,'' device safety alerts, (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video-oriented conferencing and electronic submissions, mammography matters, and other device-oriented information. The CDRH home page may be accessed at ''http://www.fda.gov/CDRH''. Information on the GHTF may be accessed at http://www.GHTF.org''.

III. Comments

Interested persons may, on or before September 30, 1999, submit to the Dockets Management Branch (address above) written comments regarding the draft documents. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with docket number found in brackets in the heading of this document and with the full title of these documents. The draft documents and received comments may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

After September 30, 1999, written comments regarding the draft documents may be submitted at any time to the contact person (address above).

Dated: July 25, 1999.

Linda S. Kahan,

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

[FR Doc. 99–20367 Filed 8–6–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97D–0302]

Guidance For Industry on Consumer-Directed Broadcast Advertisements; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a final guidance for industry entitled ''Consumer-Directed Broadcast Advertisements.'' The agency sought public comment on a draft version of this guidance, which was announced in the **Federal Register** of August 12, 1997. The agency considered the comments received and, where appropriate, revised the draft guidance. The final guidance describes how consumer-directed broadcast advertisements for prescription drugs for humans and animals, and human biological products, may comply with the requirement that they make adequate provision for dissemination of the approved package labeling.

DATES: Written comments on the final guidance may be submitted at any time.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit written requests for copies of the final guidance to the Office of Training and Communications, Division of Communications Management, Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, http://www.fda.gov/cder/guidance/index.htm; or Office of Communication, Training,