

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.*

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## 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,

and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, <http://www.fda.gov/cber/guidelines.htm>, FAX 1-888-CBERFAX or 301-827-3844, Mail: the Voice Information System at 800-835-4709 or 301-827-1800; or Communications Staff (HFV-12), Center for Veterinary Medicine (CVM), 7500 Standish Pl., Rockville, MD 20855, 301-594-1755, <http://www.fda.gov/cvm>.

**FOR FURTHER INFORMATION CONTACT:**

Regarding prescription human drugs: Nancy M. Ostrove, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2828, or via e-mail at "ostrove@cder.fda.gov".

Regarding prescription human biological products: Toni M. Stifano, Center for Biologics Evaluation and Research (HFM-602), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3028, or via e-mail at "stifano@cber.fda.gov".

Regarding prescription animal drugs: Mukund R. Parkhie, Center for Veterinary Medicine (HFV-216), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-6642, or via e-mail at "mparkhie@bangate.fda.gov".

**SUPPLEMENTARY INFORMATION:** In the *Federal Register* of August 12, 1997 (62 FR 43171), FDA announced the availability of a draft guidance for industry concerning consumer-directed broadcast advertisements. The draft guidance was intended to describe how advertisers could fulfill their obligations under the regulations to provide consumers with necessary risk information in connection with prescription drug advertisements broadcast through general public media such as radio, television, and telephone communications systems. The prescription drug advertising regulations (§ 202.1 (21 CFR 202.1)) distinguish between print and broadcast advertisements. Print advertisements must include a "brief summary," which generally contains each risk concept in the product's approved package labeling. In contrast, advertisements broadcast through media such as television, radio, or telephone communications systems must disclose the product's major risks in either the audio or audio and visual parts of the presentation; this is sometimes called the "major statement." Sponsors of broadcast advertisements are also

required to present a brief summary, or alternatively, may make "adequate provision \* \* \* for dissemination of the approved or permitted package labeling in connection with the broadcast presentation" (§ 202.1(e)(1)). The draft guidance described and explained the rationale behind one possible multifaceted approach that would fulfill the "adequate provision" requirement.

After considering comments received by the public, FDA has revised the draft guidance and is publishing it as a final guidance. FDA notes that although the comments did not address the specific issue of telephone advertisements, the lack of a specific discussion concerning such advertisements may have led to the assumption that the same multifaceted approach appropriate for television and radio advertisements was also appropriate for telephone advertisements. Therefore, in the final guidance FDA clarified its position with regard to fulfilling the "adequate provision" requirement for telephone advertisements. Aside from the addition of this clarification and the revision of introductory language to reinforce the importance in broadcast advertisements of complying with the more general requirements of the advertising regulations, there were no major revisions to the draft guidance.

As specified in its good guidance practices policy (62 FR 8961, February 27, 1997), the agency is not obliged to specifically address every comment on a draft or final guidance. However, because this draft guidance had a substantial impact on the direct-to-consumer broadcast environment, FDA believes that discussion of the agency's response to some of the issues raised in the comments will be helpful to certain individuals and groups. Therefore, FDA has placed a document entitled "Consumer-Directed Broadcast Advertisements Guidance: Questions and Answers" in the docket with this final guidance (see docket number in brackets in the heading of this document), as well as on FDA's website at "[www.fda.gov/cder/guidance/index.htm](http://www.fda.gov/cder/guidance/index.htm)".

As discussed in the August 12, 1997, *Federal Register* notice announcing availability of the draft guidance, within 2 years of publication of this final guidance, FDA intends to evaluate its effects on the public health. At the end of this evaluation period, FDA will determine whether this guidance should be withdrawn, continued, or modified to reflect the agency's current thinking.

This guidance for industry represents the agency's current thinking on consumer-directed broadcast advertisements. It does not create or

confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Interested persons may, at any time, submit written comments on the final guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, 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 final guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: June 17, 1999.

**Margaret M. Dotzel,**

*Acting Associate Commissioner for Policy.*  
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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration [HCFA-1055-NC]

#### Medicare and Medicaid Programs; Announcement of Additional Applications From Hospitals Requesting Waivers for Organ Procurement Service Areas

**AGENCY:** Health Care Financing Administration (HCFA), HHS.

**ACTION:** Notice with comment period.

**SUMMARY:** This notice announces additional applications that we have received from hospitals requesting waivers from entering into agreements with their designated organ procurement organizations. Section 1138(a)(2) of the Social Security Act allows the Secretary of the Department of Health and Human Services to grant waivers to hospitals that want to enter into an agreement with a specific OPO that is not the designated OPO for the hospital's service area. This notice requests comments from OPOs and the general public for our consideration in determining whether these waivers should be granted.

**COMMENT DATE:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on October 8, 1999.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health