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Certifier	M. W. Bell

**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.

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**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 The agency considered the comments received and, where appropriate, revised the draft guidance.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 (HFM-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.

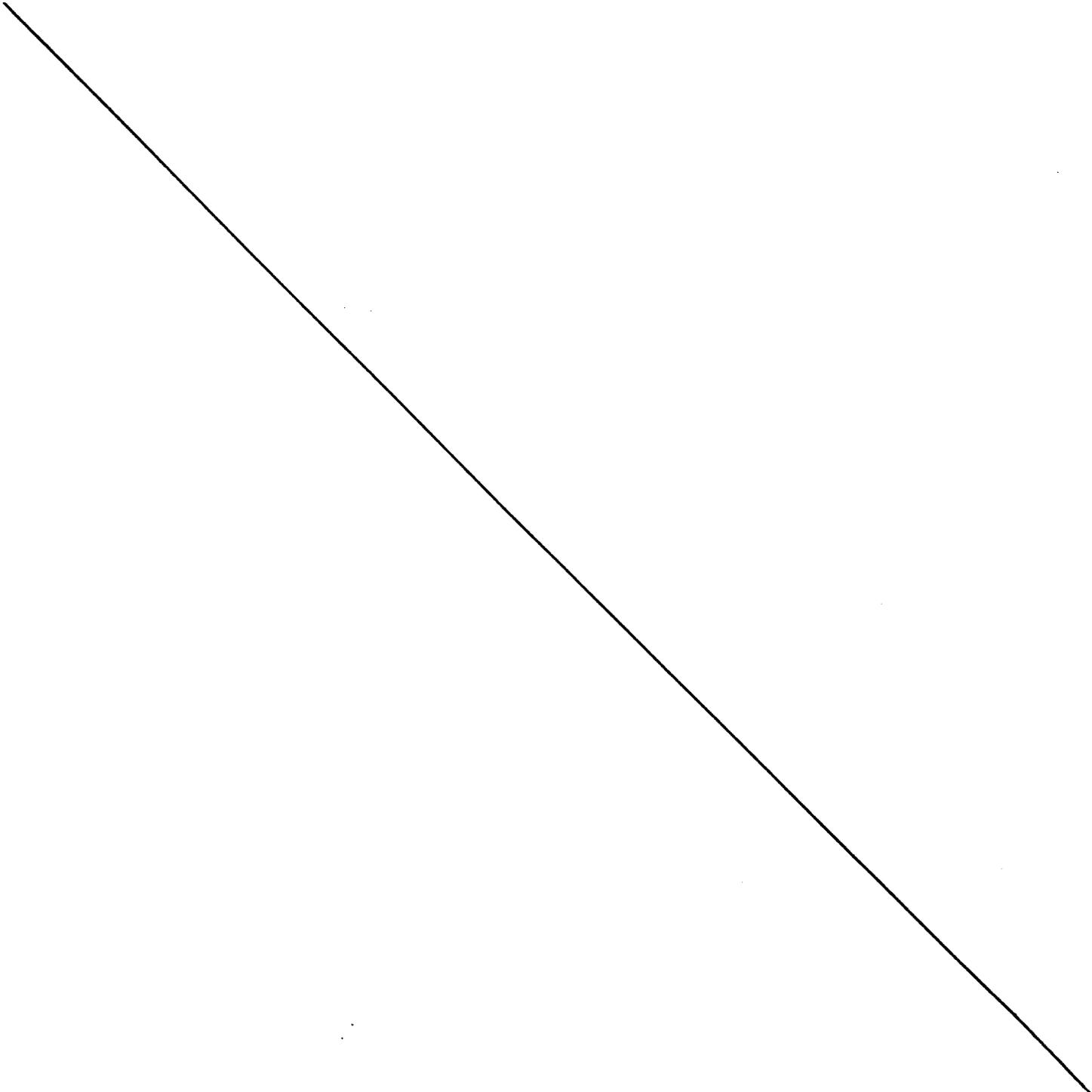
As specified in its good guidance practices policy (62 FR 8961, February 27, 1997), the agency is not obliged to specifically address every comment on a draft or final guidance. However, because this draft guidance had a substantial impact on the direct-to-consumer broadcast environment, FDA believes 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.

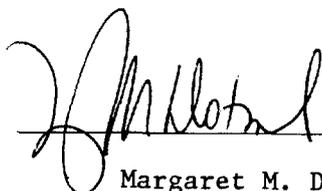
Interested persons may, at any time, submit written comments on the final guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the 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: 6/17/99

June 17, 1999



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy Coordination

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