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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-0254]

Draft Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling." This draft guidance modifies a previous guidance issued by the Division of Drug Marketing, Advertising, and Communications (DDMAC). It documents the applicability of the previous guidance to animal prescription drugs and biologic products.

DATES: Written comments on the draft guidance may be submitted by (*insert date 60 days after date of publication in the Federal Register*).

ADDRESSES: Submit written requests for single copies of the draft guidance for industry entitled "Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling" to: (1) The Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857; or (2) the Office of Communications, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448; or (3) the Communication Staff, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on this draft guidance to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT:

For information on the content of the draft guidance: Melissa M. Moncavage, Center for Drug Evaluation and Research (HFD-40), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2828, e-mail “moncavage@cder.fda.gov”; or

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, e-mail “stifano@A1.cber.fda.gov”; or

Mukund R. Parkhie, Center for Veterinary Medicine (HFV-216, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-6642, e-mail “mparkhie@bangate.fda.gov”.

SUPPLEMENTARY INFORMATION:

I. Background

DDMAC is currently reissuing guidances pertaining to prescription drug advertising and promotional labeling. These guidances have been issued to the pharmaceutical industry at various times since 1970, usually as letters or guidance papers. In the **Federal Register** of March 28, 1997 (62 FR 14912), FDA published a notice listing all previous guidances and indicating whether the agency believed they were obsolete or needed revision. Under section II.B.3 of that document, FDA listed a guidance, issued in April 1994, that needed revision. The guidance addressed placement, size, and prominence of the proprietary (brand) name and established (generic) name in advertising and labeling of prescription drug products.

This draft revision of that guidance for industry is entitled “Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.” It has been revised in the following ways: (1) It modifies the format of the guidance issued in April 1994; (2) it adds new sections to discuss the applicability of the guidance to audiovisual, broadcast, and computer-based

advertisements, and promotional labeling; (3) it adds a new section to discuss the placement, size, and prominence of the proprietary (brand) name and established (generic) name for products with two or more active ingredients; and (4) it documents the applicability of this guidance to animal prescription drugs and biologic products.

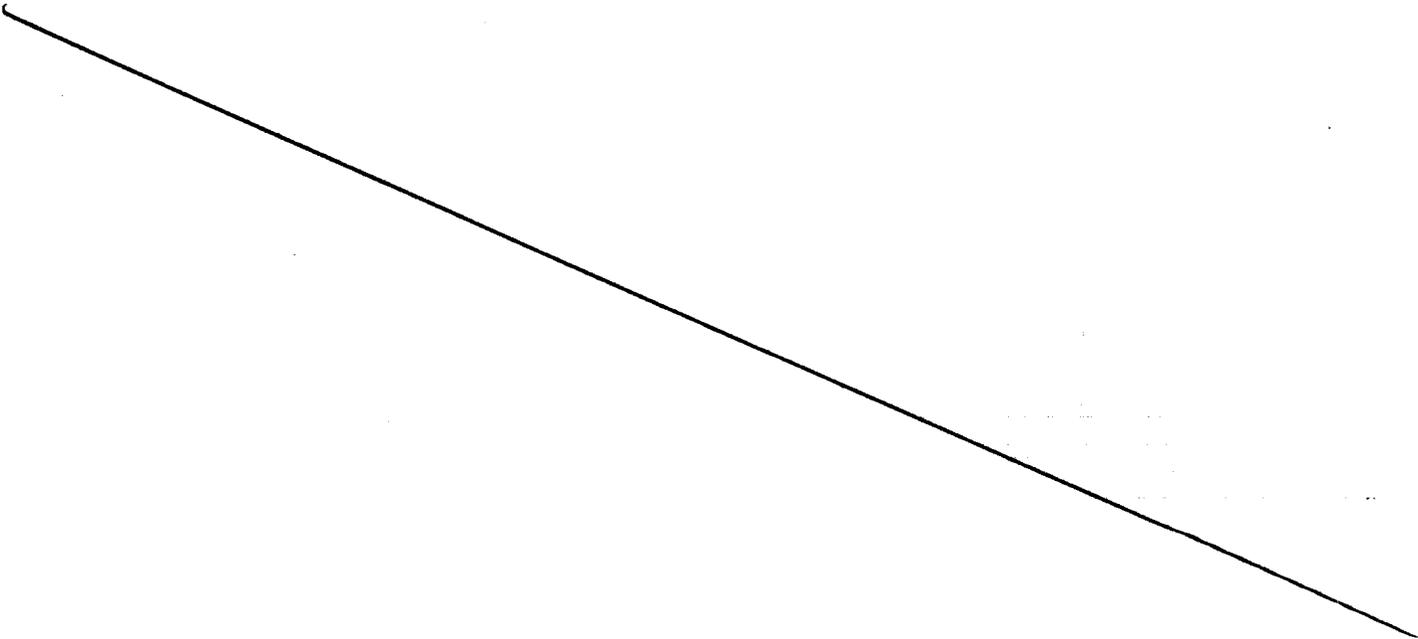
This draft guidance for industry represents the agency's current thinking on proprietary and established name placement, size, and prominence in advertising and promotional labeling. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirement of the applicable statute, regulations, or both.

II. Electronic Access

Copies of this draft guidance are available on the Internet at "<http://www.fda.gov/cder/guidance/index.htm>" or "<http://www.fda.gov/cber/guidelines.html>" or "<http://www.fda.gov/cvm>".

III. Comments

Interested persons may, on or before (*insert date 60 days after date of publication in the Federal Register*), submit to the Dockets Management Branch (address above) written comments on the draft guidance. 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



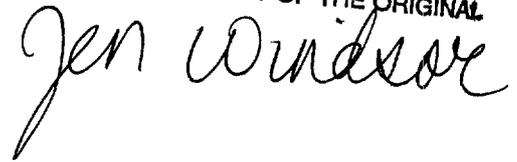
in the heading of this document. The draft guidance and received comments are available for public examination in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1999
March 5, 1999



William K. Hubbard
Acting Deputy Commissioner for
Policy

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL



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