Guidance for Industry

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

DRAFT GUIDANCE

This guidance is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact (CDER) Melissa Moncavage 301-927-2828, (CBER) Toni Stifano (301) 827-3028, or (CVM) Mukund R. Parkhie 301-827-6642

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
January 1999
DDMAC #

Guidance for Industry

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

Additional copies are available from:

Additional copies are available from:
the Drug Information Branch (HFD-210),
Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
Internet at http://www.fda.gov/cder/guidance/index.htm

or

Office of Communication,
Training, and Manufacturers Assistance (HFM-40)
Center for Biologics Evaluation and Research (CBER)
1401 Rockville Pike, Rockville, MD 20852-1448
http://www.fda.gov/cber/guidelines.htm
(Fax) 888-CBERFAX or 301-827-3844
(Voice Information) 800-835-4709 or 301-827-1800

or
Communications Staff (HFV-12),
Center for Veterinary Medicine (CVM)
7500 Standish Place, Rockville, MD 20855 (Tel) 301-594-1755
Internet at http://www.fda.gov/cvm

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)
Center for Veterinary Medicine (CVM)
January 1999
DDMAC #

TABLE OF CONTENTS

Draft - Not for Implementation

GUIDANCE FOR INDUSTRY[1]

Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

I. INTRODUCTION

This guidance is intended to clarify for applicants the requirements for product name placement, size, and prominence in labeling and advertising for human and animal prescription drugs and biological products. The disclosure of established names and ingredients in promotional labeling and advertising for all prescription human and animal drug and biological products is important for the proper identification of such products to help ensure their safe and effective use.

The Division of Drug Marketing, Advertising, and Communications (DDMAC), Center for Drug Evaluation and Research (CDER), the Division of Epidemiology and Surveillance (DES), Center for Veterinary Medicine (CVM), and the Advertising and Promotional Labeling Staff (APLS), Center for Biologics Evaluation and Research (CBER) frequently address violations and inquiries about the placement, size, and prominence of the proprietary name and established name[2] in promotional materials. Generally, the violations and inquiries address two topics: (1) the juxtaposition of the proprietary and established names in relation to certain graphic presentations and (2) problems that stem from obscuring the presentation of, or minimizing disclosure of, the established name.

The placement and prominence of the proprietary and established names for human and animal prescription drug products are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h), 202.1(b) and (c)). These regulations are applicable to human and animal prescription drug products that contain either a single active ingredient or two or more active ingredients.

For biological products, the regulations regarding position and prominence of the trade name and proper name of products, as described in 21 CFR 610.62, apply only to the container and package labels. The regulations for drug products under 21 CFR 201.10(g) and (h) and 21 CFR 202.1(b)

---

[1]This guidance has been prepared by the Intra-Agency Working Group on Advertising and Promotion at the Food and Drug Administration. This guidance represents the Agency's current thinking on product name placement, size, and prominence in advertising and labeling for human and animal prescription drugs and biologics. 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 stature, regulations, or both.

[2]As referenced in the regulations under 21 CFR 610.62, the trade name for a biological product is synonymous with the proprietary name for drug products, and the proper name for a biological product is synonymous with the established name for drug products.

and (c) apply to all other biological product labeling and advertising materials.

II. PRODUCTS WITH ONE ACTIVE INGREDIENT

A. Juxtaposition of Proprietary Name and Established Name

For products with one active ingredient, the regulations describe when and how the established name must accompany the proprietary name in the product labeling and advertising (21 CFR 201.10(g)(1), 202.1(b)(1), and 21 CFR 610.62). The regulations provided under 21 CFR 201.10(g)(1) and 202.1(b)(1) state that:

> where the established name is required to accompany or to be used in association with the proprietary name or designation, the established name shall be placed in **direct conjunction** with the proprietary name or designation, and the relationship between the proprietary name or designation and the established name shall be made clear by use of a phrase such as "brand of" preceding the established name, by brackets surrounding the established name, or by other suitable means. (Emphasis added).

FDA interprets this provision as precluding separation of the proprietary or trade name and the established or proper name by placement of a logo, trademark, or other graphic matter, or otherwise physically separating the proprietary and established name. The established or proper name should be placed either directly to the right of or directly under the proprietary name. There should be no intervening matter that in any way would detract, obfuscate, or de-emphasize the established or proper name of the product.

B. Size of Proprietary and Established Names

The regulations also require that, in general, the proprietary and established names be presented in the same size type in the running text of advertisements and promotional labeling. However, if the proprietary name is presented in some other location, such as in a headline or in larger sized type in running text, "[t]he established name shall be printed in letters that are at least half as large as the letters comprising the proprietary name or designation with which it is joined" (21 CFR 201.10(g)(1) and (2) and 202.1(b)(1) and (2))."

This print size requirement relates to actual size, not point size, of upper case and lower case letters in the proprietary and established names. For example, if the proprietary name were printed in all upper case letters, the established name should be printed in letters at least one half the actual size of the proprietary name letters. The size of the established

name letters should be independent of whether the established name is printed in upper- or lower-case letters.

C. Prominence of Proprietary and Established Names

The regulations require that "the established name shall have a prominence commensurate with the prominence with which such proprietary name or designation appears, taking into account all pertinent factors, including typography, layout, contrast, and other printing features" (21 CFR 201.10(g)(2) and 202.1(b)(2)).

These requirements include all methods used in printed promotional materials to provide emphasis, including type size, spacing, and contrast.

D. Proprietary and Established Names in Audio-Visual and Broadcast Advertisements and Promotional Labeling

The requirements for juxtaposition, size, and prominence of proprietary and established names in advertising and promotional labeling also apply to audio-visual promotional labeling and visual broadcast advertisements. When the proprietary name is displayed most prominently during audio-visual promotional labeling and broadcast advertisements, the established name should be displayed simultaneously and with a size and prominence as described in sections B and C, above. The established name should also have the same exposure time as the proprietary name.

E. Proprietary and Established Names in the Running Text of Electronic and Computer-based Advertisements and Promotional Labeling

1. Proprietary and Established Name in the Same Type Size as the Running Text

The regulations for prescription drug labeling and advertising in 21 CFR 201.10(g)(1) and 202.1(b)(1) state:

> On any page of an advertisement [labeling] in which the proprietary name or designation is not featured but is used in the running text, the established name shall be used at least once in the running text in association with such proprietary name or designation and in the same type size used in the running text: . . . .

Electronic and computer-based media, such as the Internet, CD-ROM, or electronic bulletin boards, do not contain text pages as do print media. However,

promotional labeling and advertisements in such media often contain running text equivalent to many pages of printed text. Sponsors can fulfill the requirements of 21 CFR 201.10(g)(1) and 202.1(b)(1) by using one of the following approaches. Sponsors are not limited to the approaches listed below.

- The established name accompanies the proprietary name each time the proprietary name appears in the running text.
- The established name accompanies the proprietary name once in each paragraph.
- The established name accompanies the proprietary name at regular intervals throughout the running text (e.g., every fifth paragraph).
- The established name appears with the proprietary name at the beginning, middle, and end of the running text.

2. Proprietary Name in a Larger Type Size than the Running Text

When the proprietary name is used in the running text in a larger type size, the established name should be presented as stated in the regulations:

> *Provided, however,* That [sic] if the proprietary name or designation is used in the running text in larger type size, the established name shall be used at least once in association with, and in type at least half as large as the type used for, the most prominent presentation of the proprietary name or designation in such running text (21 CFR 201.10(g)(1) and 202.1(b)(1)).

III. PRODUCTS WITH TWO OR MORE ACTIVE INGREDIENTS

A product with two or more active ingredients might not have an established name corresponding to the proprietary name. In such instances, the regulations (21 CFR 201.10(h)(1) and 202.1(c)) provide that:

> the quantitative ingredient information required on the label by section 502(e) of the act [in the advertisement by section 502(n) of the Act] shall be placed in ***direct conjunction*** with the most prominent display of the proprietary name or designation. The prominence of the quantitative ingredient information shall bear a reasonable relationship to the prominence of the proprietary name. (Emphasis added.)