Guidance for Industry

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

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)

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Advertising

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Office of Communications, Division of Drug Information, HFD-240
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002
Tel: 301-796-3400; Fax: 301-847-8714; E-mail: druginfo@fda.hhs.gov
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and

Office of Communication, Outreach, and Development, HFM-40
Center for Biologics Evaluation and Research
Food and Drug Administration
1401 Rockville Pike
Rockville, MD 20852-1448
Tel: 800-835-4709 or 301-827-1800; Fax: 301-827-3843; E-mail: ocod@fda.hhs.gov
http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm

and

CVM Communications Staff, HFV-12
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place
Rockville, MD 20855
Tel: 240-276-9300; Fax: 240-276-9115
http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/default.htm

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Contains Nonbinding Recommendations

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This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This guidance is intended to clarify the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human drugs, including biological drug products, and prescription animal drugs. The disclosure of the product name in promotional labeling and advertising for these products is important for their proper identification to ensure their safe and effective use.

The Office of Prescription Drug Promotion (OPDP) in the Center for Drug Evaluation and Research (CDER), the Office of Surveillance and Compliance (OSC) in the Center for Veterinary Medicine (CVM), and the Advertising and Promotional Labeling Branch (APLB) in the Center for Biologics Evaluation and Research (CBER) frequently receive inquiries about the placement, size, prominence, and frequency of the proprietary name[2] and established name[3] in promotional materials. Generally, the inquiries address two topics: (1) the juxtaposition of the

[1] This guidance was developed by the Center for Drug Evaluation and Research in coordination with the Center for Biologics Evaluation and Research and the Center for Veterinary Medicine.

[2] In this guidance, the term *proprietary name* is used to refer to both the proprietary name of a drug product and to the trade name of a biological product. The proprietary name is the exclusive name of a drug substance or drug product, regardless of registration status with the United States Patent and Trademark Office. The proprietary name for drug products is proposed by the applicant and undergoes review and final approval by FDA.

[3] In this guidance, the term *established name* is used to refer to both the established name of a drug product and to the proper name of a biological product. The established name with respect to a drug or ingredient thereof is the applicable official name designated pursuant to section 508, the official title thereof in an official compendium (if the drug or ingredient is an article recognized in an official compendium), the common or usual name (if any) of the drug or ingredient, or the name as defined by the United States Pharmacopeia or the Homeopathic Pharmacopeia. See 21 U.S.C. 352(e)(3).

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, size, prominence, and frequency of the proprietary and established names for prescription human drugs, including biological drug products, and prescription animal drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c) and (d)).[4] These regulations are applicable to prescription human and animal drug products that contain one or more active ingredient(s).

The recommendations in this guidance pertain to product names in traditional print media promotion (e.g., journal ads, detail aids, brochures), audio-visual promotional labeling (e.g., videos shown in a healthcare provider's office), broadcast media promotion (e.g., television advertisements, radio advertisements), and electronic and computer-based promotional labeling and advertisements, such as Internet promotion, social media, e-mails, CD-ROMs, and DVDs.

II. PRODUCTS WITH ONE ACTIVE INGREDIENT

A. Juxtaposition of Proprietary and Established Names

For products with one active ingredient, the regulations describe when and how the established name must accompany the proprietary name in labeling and advertising (21 CFR 201.10(g)(1) and 202.1(b)(1)). The regulations provided in 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 recommends that the established name be placed either directly to the right of, or directly below, the proprietary name. *Note*: FDA does not intend to prohibit sponsors from using trademark symbols associated with proprietary names such as registered trademark symbols ® and unregistered trademark symbols ™, or controlled substance symbols (e.g., CII). FDA also recommends that the proprietary name and the established name not be separated by placement of intervening matter that, in any way, would detract, obfuscate, or de-emphasize the established name of the product, or obscure the relationship between the proprietary name and the established name. For example, FDA recommends that the proprietary and established names not be separated by intervening matter, such as a logo, tagline, or other graphics.

[4]For biological products, 21 CFR 610.62 applies to the position and prominence of the trade name and proper name of products on the package *label*. To avoid user confusion, we recommend that the format described in 21 CFR 610.62 is also applied to the containers of biological products, such that the order of the trade name and proper name on the package and container match. Per 21 CFR 601.2(c)(1), the requirements of 21 CFR 601.62 are not applicable to a biological product that is a "therapeutic DNA plasmid product, therapeutic synthetic peptide product of 40 or fewer amino acids, monoclonal antibody product for in vivo use, or therapeutic recombinant DNA-derived product."

Examples of appropriate juxtaposition include, but are not limited to, the following:

PROPRIETARY NAME® (established name)

♠ PROPRIETARY NAME™ (established name)

PROPRIETARY NAME® CII
(established name)

B. Size of Proprietary and Established Names

When the established name is required to accompany the proprietary name, the regulations also require, in general, that the proprietary and established names be presented in the same type size in the running text of promotional labeling and advertising (21 CFR 201.10(g)(1) and 202.1(b)(1)). FDA interprets *the running text* to mean the body of text in a piece, as distinct from headlines, taglines, logos, footnotes, graphs, or pictures. When the proprietary name is presented outside the running text, such as in a headline, or is presented within the running text in larger sized type than that of the surrounding running text, the established name is required to be printed in letters that are at least half as large as the letters of the proprietary name (21 CFR 201.10(g)(1) and (2); 202.1(b)(1) and (2)).

This type size requirement relates to actual size, not point size, of upper case and lower case letters in the proprietary and established names. For example, in situations when the established name is required to be printed in letters at least half as large as the letters of the proprietary name, FDA recommends that the smallest letter of the established name (upper or lower case letters) be printed in letters at least one half the actual size of the largest letter of the proprietary name (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)).

FDA considers all methods used in promotional labeling or advertising to provide emphasis, including but not limited to type size, spacing, and contrast, when evaluating whether the established name is presented with a prominence commensurate with the prominence of the presentation of the proprietary name. For example, if the proprietary name is printed in bold black text against a white background, FDA recommends that the established name be presented with commensurate emphasis and contrast.

D. Frequency of Disclosure of Proprietary and Established Names

The regulations at 21 CFR 201.10(g)(1) and 202.1(b)(1) state that:

> If an advertisement [or the label or labeling of] for a prescription drug bears a proprietary name or designation for the drug or any ingredient thereof, the established name, if such there be, corresponding to such proprietary name or designation shall accompany such proprietary name or designation each time it is featured in the advertisement [or on the label or in the labeling] for the drug . . . . On any page of an advertisement [or any label or page of 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 . . . . If any advertisement [or any labeling] includes a **column** with running text containing detailed information as to composition, prescribing, side effects, or contraindications and the proprietary name or designation is used in such column but is not featured above or below the column, the established name shall be used at least once in such column of running text in association with such proprietary name or designation . . . . (Emphasis added)

1. Traditional Print Promotional Labeling and Advertisements

For traditional print promotional labeling and advertisements, if the proprietary name is ***not*** part of the running text (e.g., headlines, taglines, logos, footnotes, graphs, or pictures), the established name is required to accompany the proprietary name each time the proprietary name appears. If the proprietary name is part of the running text, the established name is required to accompany the proprietary name at least once in the running text. If the running text spans more than one page, FDA recommends that the established name accompany the proprietary name at least once per page.

The above regulations include information regarding the frequency of the proprietary and established names if columns are used in a promotional labeling piece or advertisement (e.g., a newspaper advertisement). FDA interprets *a column* to mean one of two or more vertical sections of a printed page, separated by a rule or blank space. If the proprietary name appears in more than one column of running text (but does not appear outside of the text, above or below the column), the established name should accompany the proprietary name at least once per column. If the column spans more than one page, FDA recommends that the established name accompany the proprietary name at least once per page.

2. Audio-Visual Promotional Labeling and Broadcast Advertisements

Audio-visual promotional labeling and audio-visual broadcast advertisements (i.e., television ads) do not contain text pages like print media. However, promotional labeling and advertising in such media often contain superimposed text or "supers." For superimposed text that is equivalent to a headline or tagline, sponsors can fulfill the requirements of 21 CFR 201.10(g)(1) and 202.1(b)(1) by placing the established name in direct conjunction with the most prominent display of the proprietary name in the audio-visual promotional labeling or broadcast advertisement. When the established name accompanies the proprietary name, FDA recommends that the established name be displayed on the screen for the same amount of time as the proprietary name. For superimposed text that typically runs along the bottom of the screen, the established name does not have to be included with the proprietary name. FDA also recommends that the established name be included in the audio portion of the labeling or advertisement with the most prominent display of the proprietary name. Under most circumstances, this is the first occurrence in the broadcast.

For radio and telephone advertisements, sponsors can fulfill the requirements of 21 CFR 202.1(b)(1) by placing the established name in direct conjunction with the most prominent presentation of the proprietary name. Under most circumstances, this is the first occurrence in the broadcast.

3. Electronic and Computer-Based Promotional Labeling and Advertisements

Promotional labeling and advertising in electronic and computer-based media also do not contain text pages like print media. However, promotional labeling and advertising in such media often contain running text equivalent to many pages of traditional printed text. If the proprietary name is ***not*** part of the running text (e.g., headlines, taglines, logos, footnotes, graphs, or pictures), the established name is required to accompany the proprietary name each time the proprietary name appears. If the proprietary name is part of the running text, the established name is required to accompany the proprietary name at least once in the running text. If the running text spans more than one screen, FDA recommends that the established name accompany the proprietary name at least once per screen.

III. PRODUCTS WITH TWO OR MORE ACTIVE INGREDIENTS

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

> [T]he quantitative ingredient information required on the label by section 502(e) of the act [or 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)

Similarly, a product with one proprietary name might refer to a combination of active ingredients present in more than one preparation (e.g., individual preparations differing from each other as to quantities of active ingredients and/or the form of the finished preparation), and there might not be an established name corresponding to the proprietary name. In such instances, the advertising regulations (21 CFR 202.1(d)(1)) provide that:

> [A] listing showing the established names of the active ingredients shall be placed in **direct conjunction** with the most prominent display of such proprietary name or designation. The prominence of this listing of active ingredients shall bear a reasonable relationship to the prominence of the proprietary name and the relationship between such proprietary name or designation, and the listing of active ingredients shall be made clear by use of such phrase as "brand of", preceding the listing of active ingredients. (Emphasis added)

In both of these situations, FDA recommends that the active ingredients be placed either directly to the right of or directly under the proprietary name. *Note*: FDA does not intend to prohibit sponsors from using trademark symbols associated with proprietary names such as registered

trademark symbols ® and unregistered trademark symbols ™, or controlled substance symbols (e.g., CII). FDA also recommends that the proprietary name and the required information regarding the active ingredients not be separated by placement of intervening matter that in any way would detract, obfuscate, or de-emphasize the active ingredients of the product, or obscure the relationship between the proprietary name and the active ingredients. For example, FDA recommends that the proprietary name and the required information regarding the active ingredients not be separated by intervening matter, such as a logo, tagline, or other graphics.

Examples of appropriate juxtaposition include, but are not limited to, the following:

PROPRIETARY NAME® (active ingredient 1 and active ingredient 2)

♠ PROPRIETARY NAME™ (active ingredient 1 and active ingredient 2)

PROPRIETARY NAME® CII
active ingredient 1/active ingredient 2

The regulations described above also require that the presentation of the active ingredients "bear a reasonable relationship to the prominence of the proprietary name" (21 CFR 201.10(h)(1) and 202.1(c)). Thus, FDA recommends that the active ingredients be presented with a prominence commensurate with the prominence of the presentation of the proprietary name. For example, if the proprietary name is printed in bold black text against a white background, FDA recommends that the active ingredients be presented with commensurate emphasis and contrast.