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

Guidance for Industry

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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The information collection provisions in this guidance regarding third-party disclosure are under OMB review and are not for current implementation.
See additional PRA statement in section IV of this guidance.

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Additional copies are available from:

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Contains Nonbinding Recommendations

Product Name Placement, Size, and Prominence in Promotional Labeling and Advertisements Guidance for Industry[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This guidance clarifies the requirements for product name placement, size, prominence, and frequency[2] in promotional labeling and advertisements for prescription drugs.[3] The disclosure of the product name in promotional labeling and advertisements is important for proper identification and to ensure safe and effective use. This guidance also articulates the circumstances under which FDA intends to refrain from taking enforcement action regarding these requirements. We believe that following this guidance will allow for appropriate advertising and promotion without presenting any public health risk to patients.

The Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research; the Office of Surveillance and Compliance in the Center for Veterinary Medicine; and the Advertising and Promotional Labeling Branch in the Center for Biologics Evaluation and Research frequently receive inquiries about the placement, size, prominence, and frequency of the proprietary name[4] and established name[5] in promotional materials (promotional labeling and

[1] This guidance has been prepared by the Office of Prescription Drug Promotion in the Center for Drug Evaluation and Research in coordination with the Center for Biologics Evaluation and Research and the Center for Veterinary Medicine at the Food and Drug Administration.

[2] See 21 CFR 201.10(g) and (h) and 202.1(b), (c), and (d).

[3] For the purposes of this guidance, the term *prescription drug* means human prescription drugs, including prescription biological products, and animal prescription drugs. With respect to biological products, the recommendations in this guidance apply to biological products that are approved for marketing under section 351 of the Public Health Service Act (PHS Act) and that are also regulated under the drug provisions of the Federal Food, Drug, and Cosmetic Act (FD&C Act). For such products, the provisions of the FD&C Act applicable to drugs also apply, as well as the regulations implementing these provisions, except that a biological product licensed under section 351 of the PHS Act is not required to have an approved new drug application under section 505 of the FD&C Act (21 U.S.C. 355). See section 351(j) of the PHS Act (42 U.S.C. 262(j)). This guidance does not apply to over-the-counter drugs.

[4] In this guidance, the term *proprietary name* refers to the trademark or brand name of a drug or biological product. The proprietary name is the exclusive name of a drug or biological product owned by a company under trademark law regardless of registration status with the United States. Patent and Trademark Office. The proprietary name for

advertisements). Generally, the 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, size, prominence, and frequency of the proprietary and established names for prescription drugs are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h) and 202.1(b), (c) and (d)). These regulations are applicable to prescription drugs that contain one or more active ingredient(s).

The recommendations in this guidance pertain to product names in traditional print media promotional labeling and advertisements (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g., videos shown in a health care provider's office), broadcast advertisements (e.g., television advertisements, radio advertisements), and electronic and computer-based promotions (e.g., internet, social media, emails, CD-ROMs, DVDs). In this guidance, FDA further clarifies issues relating to the direct conjunction of the proprietary and established names, as well as the frequency of use of the established name on printed pages or spreads, in running text or columns, in the audio portion of audiovisual promotions, and in electronic media.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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 advertisements. The regulations 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

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prescription drug and biological products is proposed by the applicant and undergoes review and final approval by FDA.

[5] In this guidance, the term *established name* refers 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 product or ingredient thereof is the applicable official name designated pursuant to section 508 of the FD&C Act; or if there is no such official name, and such drug, or such ingredient, is an article recognized in an official compendium (such as the United States Pharmacopeia), then the official title thereof in such compendium; or if neither applies, the drug product's or ingredient's common or usual name (*see* 21 U.S.C. 352(e)(3)). The proper name of a biological product is the name designated in the license for use upon each package of the product (21 CFR 600.3(k)).

> 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. FDA also recommends that the proprietary name and the established name not be separated by placement of intervening matter that would in any way detract from, 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. *Note*: FDA does not consider trademark symbols associated with proprietary names (e.g., registered trademark symbols (®) or unregistered trademark symbols (™)) or controlled substance symbols (e.g., CII) to be intervening matter.

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

PROPRIETARY NAME® (established name)

♠[6] 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 in the running text of promotional labeling and advertisements, the regulations also require, in general, that the proprietary and established names be presented in the same type size (21 CFR 201.10(g)(1) and 202.1(b)(1)). FDA interprets *the running text* to mean the body of text in a promotional piece, as distinct from headlines, taglines, logos, graphs, or pictures.

When the proprietary name 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 at least once in letters that are at least half as large as the letters of the most prominent presentation of the proprietary name in such running text (21 CFR 201.10(g)(1) and (2) and 202.1(b)(1) and (2)). In addition, when the proprietary name is presented outside the running text, such as in a headline, the established name is also required to be printed in letters that are at least half as large as the letters of the proprietary name within that designated section (e.g., headline) (21 CFR 201.10(g)(1) and (2) and 202.1(b)(1) and (2)).

Please note that FDA interprets this type-size requirement to relate to actual size, not point size, of uppercase and lowercase 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

[6] The "♠"symbol represents a logo or graphic representation.

name (upper- or lowercase letters) be printed in letters at least one half the actual size of the largest letter of the proprietary name (upper- or lowercase 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)). Generally, FDA considers all methods used to achieve prominence in promotional labeling or advertisements when evaluating whether the established name is presented with a prominence commensurate with that of the proprietary name.

The following hypothetical examples[7] of established name presentations do not have commensurate prominence with the proprietary names, considering factors such as contrast, type size, and spacing:

D. Frequency of Disclosure of Proprietary and Established Names

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

> If an advertisement for [or the label or labeling of] 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, the established name is required to accompany the proprietary name when the proprietary name is featured (e.g., headlines, taglines, logos, graphs, or pictures). Although the regulations state that the established name "shall

[7] The examples involve fictitious products and are not an endorsement of the fictitious product names.

accompany such proprietary name . . . each time it is featured," FDA does not intend to object to fewer appearances of the established name, provided that the established name accompanies the proprietary name at least once per page or spread[8] where the proprietary name most prominently appears. For example, if the established name follows the proprietary name in a headline, FDA does not intend to object if the established name does not also follow the proprietary name in sub-headlines, appear in the running text on the same page or spread, or appear in columns on the same page or spread.

If the proprietary name is not featured but is only 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 or spread, FDA recommends that the established name accompany the proprietary name at least once per page or spread.

The regulations in 21 CFR 201.10(g)(1) and 202.1(b)(1) 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), FDA does not intend to object, provided that the established name accompanies the proprietary name at least once per page or spread.

2. Audiovisual Promotional Labeling and Broadcast Advertisements

Audiovisual promotional labeling (e.g., videos shown in a health care provider's office) and audiovisual broadcast advertisements (e.g., television ads) do not contain text pages like print media. However, promotional labeling and advertisements in such media often contain superimposed text or "supers." For superimposed text that is equivalent to a headline or tagline, FDA does not intend to object to fewer appearances of the established name if the established name is placed in direct conjunction with the most prominent display of the proprietary name in the audiovisual promotional labeling or broadcast advertisement.[9] 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 appears along the bottom of the screen, the established name does not have to be included with the proprietary name. FDA does not intend to object if the established name is not included in the audio portion of audiovisual promotional labeling or in an audiovisual broadcast advertisement.

For radio and telephone advertisements, FDA does not intend to object if the established name is disclosed in direct conjunction with the most prominent presentation of the proprietary name. Under most circumstances, this is the first occurrence in the broadcast.

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[8] In this guidance, the term *spread* refers to adjacent pages of promotional material with related matter or connecting elements extending across the fold.

[9] When determining the most prominent display of the proprietary name, consideration should be given to all pertinent factors, including typography, layout, contrast, and other printing features, such as type size. The most prominent display of the proprietary name is generally the largest display in audiovisual promotional labeling and broadcast advertisements.

3. Electronic and Computer-Based Promotion

Promotion in electronic and computer-based media also does not contain text pages like print media. However, promotion in such media often contains information or running text equivalent to many pages of traditional printed text. FDA does not intend to object to fewer appearances of the established name, provided that the established name accompanies the proprietary name at least once per web page where the proprietary name most prominently appears on the web page.[10] However, if the proprietary name is not featured but is part of the running text, the established name is required to accompany the proprietary name at least once in the running text (21 CFR 201.10(g)(1) and 202.1(b)(1)). Columns of running text should be treated similarly to columns on the printed page.

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 in 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 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 in 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 below the proprietary name. FDA also recommends that the proprietary name and the required information regarding the active ingredients not be separated

[10] When determining the most prominent display of the proprietary name, consideration should be given to the placement of the proprietary name and how the web page is displayed when viewed on different devices (e.g., desktop computer monitors, mobile devices, tablets). The most prominent display of the proprietary name is generally near the top of the relevant web page when viewed on most electronic devices.

by placement of intervening matter that would in any way detract from, 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. As noted in section II.A of this guidance, FDA does not consider trademark symbols associated with proprietary names (e.g., registered trademark symbols (®) or unregistered trademark symbols (™)) or controlled substance symbols (e.g., CII) to be intervening matter.

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 in this section 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.

IV. PAPERWORK REDUCTION ACT OF 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The time required to complete this information collection is estimated to average 3 hours per disclosure. Send comments regarding this burden estimate or suggestions for reducing this burden to:

Office of Prescription Drug Promotion, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, Silver Spring, MD 20993-0002

This guidance also refers to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR 202.1 have been approved under OMB control number 0910-0686.

An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The information collection provisions in this guidance have been submitted to OMB for review as required by

section 3507(d) of the Paperwork Reduction Act of 1995 **and are not for current implementation**. Before implementing the information collection provisions contained in this guidance, we will publish a notice in the *Federal Register* announcing OMB's decision to approve, modify, or disapprove those information collection provisions.