
Guidance for Industry Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.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be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance.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 electronic comments to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (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 regarding this draft document contact (CDER) Cynthia Ng at 301-796-1200 or (CBER) Stephen Ripley at 301-827-6210 or (CVM) Thomas Moskal at 240-276-9242.

**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)**

**November 2013
Advertising
Revision 1**

Guidance for Industry Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling

Additional copies are available from:

*Office of Communications
Division of Drug Information, WO51, Room 2201
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Ave., Silver Spring, MD 20993
Phone: 301-796-3400; Fax: 301-847-8714*

druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

and/or

*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*

<http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

(Tel) 800-835-4709 or 301-827-1800

and/or

*Communications Staff, HFV-12
Center for Veterinary Medicine
Food and Drug Administration
7519 Standish Place, Rockville, MD 20855
(Tel) 240-276-9300*

<http://www.fda.gov/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/default.htm>

**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)**

**November 2013
Advertising
Revision 1**

Contains Nonbinding Recommendations

Draft — Not for Implementation

TABLE OF CONTENTS

| | |
|---|----------|
| I. INTRODUCTION..... | 1 |
| II. PRODUCTS WITH ONE ACTIVE INGREDIENT..... | 2 |
| A. Juxtaposition of Proprietary and Established Names | 2 |
| B. Size of Proprietary and Established Names..... | 3 |
| C. Prominence of Proprietary and Established Names | 4 |
| D. Frequency of Disclosure of Proprietary and Established Names | 4 |
| 1. <i>Traditional Print Promotional Labeling and Advertisements</i> | 4 |
| 2. <i>Audiovisual Promotional Labeling and Broadcast Advertisements</i> | 5 |
| 3. <i>Electronic and Computer-Based Promotion</i> | 5 |
| III. PRODUCTS WITH TWO OR MORE ACTIVE INGREDIENTS..... | 6 |

Contains Nonbinding Recommendations

Draft — Not for Implementation

Guidance for Industry¹

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

This draft guidance, when finalized, will represent 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 revised guidance clarifies 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.² The disclosure of the product name in promotional labeling and advertising for these products is important for proper identification and to ensure safe and effective use. This revised guidance also articulates the circumstances under which FDA intends to exercise enforcement discretion regarding these requirements. We believe that following this guidance will allow for appropriate advertising and promotion without presenting any additional public health risk to patients.

In this revised guidance, FDA further clarifies issues relating to the following: intervening matter, appropriate use of the established name on pages or spreads, use of the established name in running text or columns, use of the established name in the audio portion of audiovisual promotions, and presentation of the established name on Web pages or electronic screens.

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 name³ and established name⁴ in

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

² See 21 CFR 201.10(g) and (h); 202.1(b), (c) and (d). This guidance only applies to the requirements for product name placement, size, prominence, and frequency in advertising and promotional labeling materials for prescription human drugs, including biological drug products, and prescription animal drugs.

³ 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

Contains Nonbinding Recommendations

Draft — Not for Implementation

37 promotional materials. Generally, the inquiries address two topics: (1) the juxtaposition of the
38 proprietary and established names in relation to certain graphic presentations and (2) problems
39 that stem from obscuring the presentation of, or minimizing disclosure of, the established name.
40

41 The placement, size, prominence, and frequency of the proprietary and established names for
42 prescription human drugs, including biological drug products, and prescription animal drugs are
43 specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c) and
44 (d)).⁵ These regulations are applicable to prescription human and animal drug products that
45 contain one or more active ingredient(s).
46

47 The recommendations in this revised guidance pertain to product names in traditional print
48 media promotion (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling
49 (e.g., videos shown in a health care provider's office), broadcast media promotion (e.g.,
50 television advertisements, radio advertisements), and electronic and computer-based promotion,
51 (e.g., Internet promotion, social media, emails, CD-ROMs, and DVDs).
52

53 FDA's guidance documents, including this revised guidance, do not establish legally enforceable
54 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
55 be viewed only as recommendations, unless specific regulatory or statutory requirements are
56 cited. The use of the word *should* in Agency guidances means that something is suggested or
57 recommended, but not required.
58

59 II. PRODUCTS WITH ONE ACTIVE INGREDIENT

60 A. Juxtaposition of Proprietary and Established Names

61
62
63 For products with one active ingredient, the regulations describe when and how the established
64 name must accompany the proprietary name in labeling and advertising (21 CFR 201.10(g)(1)
65 and 202.1(b)(1)). The regulations provided in 21 CFR 201.10(g)(1) and 202.1(b)(1) state that:
66

67 Where the established name is required to accompany or to be used in association with
68 the proprietary name or designation, the established name shall be placed in **direct**

product, regardless of registration status with the United States Patent and Trademark Office. The proprietary name for prescription drug products is proposed by the applicant and undergoes review and final approval by FDA.

⁴ 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 product or ingredient thereof is the applicable official name designated pursuant to section 508 of the Federal Food, Drug, and Cosmetic Act, or if there is no such official name, the title of any related official United States Pharmacopeia drug product or drug substance (ingredient) monograph, 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)).

⁵ 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 also be 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."

Contains Nonbinding Recommendations

Draft — Not for Implementation

69 **conjunction** with the proprietary name or designation, and the relationship between the
70 proprietary name or designation and the established name shall be made clear by use of a
71 phrase such as “brand of” preceding the established name, by brackets surrounding the
72 established name, or by other suitable means. (Emphasis added)
73

74 FDA recommends that the established name be placed either directly to the right of, or directly
75 below, the proprietary name. FDA also recommends that the proprietary name and the
76 established name not be separated by placement of intervening matter that in any way would
77 detract, obfuscate, or de-emphasize the established name of the product, or obscure the
78 relationship between the proprietary name and the established name. For example, FDA
79 recommends that the proprietary and established names not be separated by intervening matter,
80 such as a logo, tagline, or other graphics. *Note:* FDA does not consider trademark symbols
81 associated with proprietary names (e.g., registered trademark symbols ® or unregistered
82 trademark symbols ™) or controlled substance symbols (e.g., CII) to be intervening matter.
83

84 Examples of appropriate juxtaposition include, but are not limited to, the following:
85

86 PROPRIETARY NAME® (established name)
87

88 ♠⁶ PROPRIETARY NAME™ (established name)
89

90 PROPRIETARY NAME® CII
91 (established name)
92

B. Size of Proprietary and Established Names

94
95 When the established name is required to accompany the proprietary name in the running
96 text of promotional labeling and advertising, the regulations also require, in general, that
97 the proprietary and established names be presented in the same type size (21 CFR
98 201.10(g)(1) and 202.1(b)(1)). FDA interprets *the running text* to mean the body of text
99 in a promotional piece, as distinct from headlines, taglines, logos, graphs, or pictures.
100

101 When the proprietary name is presented within the running text in larger sized type than that of
102 the surrounding running text, the established name is required to be printed at least once in letters
103 that are at least half as large as the letters of the most prominent presentation of the proprietary
104 name in such running text (21 CFR 201.10(g)(1) and (2); 202.1(b)(1) and (2)). In addition, when
105 the proprietary name is presented outside the running text, such as in a headline, the established
106 name is also required to be printed in letters that are at least half as large as the letters of the
107 proprietary name within that designated section (e.g., headline) (21 CFR 201.10(g)(1) and (2);
108 202.1(b)(1) and (2).
109

110 Please note that FDA interprets this type size requirement to relate to actual size, not point size,
111 of upper case and lower case letters in the proprietary and established names. For example, in
112 situations when the established name is required to be printed in letters at least half as large as

⁶ The “♠” symbol represents a logo or graphic representation.

Contains Nonbinding Recommendations

Draft — Not for Implementation

113 the letters of the proprietary name, FDA recommends that the smallest letter of the established
114 name (upper or lower case letters) be printed in letters at least one half the actual size of the
115 largest letter of the proprietary name (upper or lower case letters).

C. Prominence of Proprietary and Established Names

117
118
119 The regulations require that “the established name shall have a prominence commensurate with
120 the prominence with which such proprietary name or designation appears, taking into account all
121 pertinent factors, including typography, layout, contrast, and other printing features” (21 CFR
122 201.10(g)(2) and 202.1(b)(2)).

123
124 FDA considers all methods used in promotional labeling or advertising to provide emphasis
125 including, but not limited, to type size, spacing, and contrast, when evaluating whether the
126 established name is presented with a prominence commensurate with the prominence of the
127 presentation of the proprietary name. For example, if the proprietary name is printed in bold
128 black text against a white background, FDA recommends that the established name be presented
129 with commensurate emphasis and contrast.

D. Frequency of Disclosure of Proprietary and Established Names

130
131
132
133 The regulations at 21 CFR 201.10(g)(1) and 202.1(b)(1) state that:

134
135 If an advertisement for [or the label or labeling of] a prescription drug bears a proprietary
136 name or designation for the drug or any ingredient thereof, the established name, if such
137 there be, corresponding to such proprietary name or designation shall accompany such
138 proprietary name or designation each time it is featured in the advertisement [or on the
139 label or in the labeling] for the drug On any page of an advertisement [or any label
140 or page of labeling] in which the proprietary name or designation is not featured but is
141 used in the running text, the established name shall be used at least once in the running
142 text in association with such proprietary name or designation If any advertisement
143 [or any labeling] includes a **column** with running text containing detailed information as
144 to composition, prescribing, side effects, or contraindications and the proprietary name or
145 designation is used in such column but is not featured above or below the column, the
146 established name shall be used at least once in such column of running text in association
147 with such proprietary name or designation (Emphasis added)

1. Traditional Print Promotional Labeling and Advertisements

148
149
150
151 For traditional print promotional labeling and advertisements, the established name is required to
152 accompany the proprietary name when the proprietary name is featured (e.g., headlines, taglines,
153 logos, graphs, or pictures). Although the regulations state that the established name “shall
154 accompany such proprietary name . . . each time it is featured,” in exercising its enforcement
155 discretion, FDA does not intend to object provided that the established name accompanies the
156 proprietary name at least once per page or spread⁷ where the proprietary name most prominently
157 appears on the page or spread. For example, if the established name follows the proprietary

⁷ In this guidance, the term *spread* is used to refer to adjacent pages of promotional material with related matter or connecting elements extending across the fold.

Contains Nonbinding Recommendations

Draft — Not for Implementation

158 name in a headline, FDA does not intend to object if the established name does not also follow
159 the proprietary name in sub-headlines, appear in the running text on the same page or spread, or
160 appear in columns on the same page or spread.

161
162 If the proprietary name is not featured but is only part of the running text, the established name is
163 required to accompany the proprietary name at least once in the running text. If the running text
164 spans more than one page or spread, FDA recommends that the established name accompany the
165 proprietary name at least once per page or spread.

166
167 The above regulations include information regarding the frequency of the proprietary and
168 established names if columns are used in a promotional labeling piece or advertisement (e.g., a
169 newspaper advertisement). FDA interprets *a column* to mean one of two or more vertical
170 sections of a printed page, separated by a rule or blank space. If the proprietary name appears in
171 more than one column of running text (but does not appear outside of the text, above or below
172 the column), FDA does not intend to object provided the established name accompanies the
173 proprietary name at least once per page or spread.

174 175 2. *Audiovisual Promotional Labeling and Broadcast Advertisements*

176
177 Audiovisual promotional labeling and audiovisual broadcast advertisements (i.e., television ads)
178 do not contain text pages like print media. However, promotional labeling and advertising in
179 such media often contain superimposed text or “supers.” For superimposed text that is
180 equivalent to a headline or tagline, FDA does not intend to object if sponsors place the
181 established name in direct conjunction with the most prominent display of the proprietary name
182 in the audiovisual promotional labeling or broadcast advertisement. When the established name
183 accompanies the proprietary name, FDA recommends that the established name be displayed on
184 the screen for the same amount of time as the proprietary name. For superimposed text that
185 typically appears along the bottom of the screen, the established name does not have to be
186 included with the proprietary name. FDA intends to exercise enforcement discretion if the
187 established name is not included in the audio portion of audiovisual promotional labeling or an
188 audiovisual broadcast advertisement.

189
190 For radio and telephone advertisements, FDA does not intend to object if sponsors disclose the
191 established name in direct conjunction with the most prominent presentation of the proprietary
192 name. Under most circumstances, this is the first occurrence in the broadcast.

193 194 3. *Electronic and Computer-Based Promotion*

195
196 Promotion in electronic and computer-based media also does not contain text pages like print
197 media. However, promotion in such media often contains information or running text equivalent
198 to many pages of traditional printed text. FDA does not intend to object provided that the
199 established name accompanies the proprietary name at least once per Web page or screen where
200 the proprietary name most prominently appears on the Web page or screen.⁸ However, if the

⁸ When determining the most prominent display of the proprietary name, consideration should be given to the placement of the proprietary name. The most prominent display of the proprietary name is generally near the top of the relevant Web page or screen on most electronic devices.

Contains Nonbinding Recommendations

Draft — Not for Implementation

201 proprietary name is not featured but is part of the running text, the established name is required
202 to accompany the proprietary name at least once in the running text (21 CFR 201.10(g)(1); 21
203 CFR 202.1(b)(1)). Columns of running text should be treated similarly to columns on the printed
204 page.

205

206 **III. PRODUCTS WITH TWO OR MORE ACTIVE INGREDIENTS**

207

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

211

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

217

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

223

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

231

232 In both of these situations, FDA recommends that the active ingredients be placed either directly
233 to the right of or directly under the proprietary name. FDA also recommends that the proprietary
234 name and the required information regarding the active ingredients not be separated by
235 placement of intervening matter that in any way would detract, obfuscate, or de-emphasize the
236 active ingredients of the product, or obscure the relationship between the proprietary name and
237 the active ingredients. For example, FDA recommends that the proprietary name and the
238 required information regarding the active ingredients not be separated by intervening matter,
239 such as a logo, tagline, or other graphics. *Note:* FDA does not consider trademark symbols
240 associated with proprietary names (e.g., registered trademark symbols ® or unregistered
241 trademark symbols ™) or controlled substance symbols (e.g., CII) to be intervening matter.

242

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

244

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

246

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

Contains Nonbinding Recommendations

Draft — Not for Implementation

248

249

PROPRIETARY NAME[®] CII

250

active ingredient 1/active ingredient 2

251

252

The regulations described above also require that the presentation of the active ingredients “bear

253

a reasonable relationship to the prominence of the proprietary name” (21 CFR 201.10(h)(1) and

254

202.1(c)). Thus, FDA recommends that the active ingredients be presented with a prominence

255

commensurate with the prominence of the presentation of the proprietary name. For example, if

256

the proprietary name is printed in bold black text against a white background, FDA recommends

257

that the active ingredients be presented with commensurate emphasis and contrast.